Longitudinal Study of Recovery Following Diaphyseal Fracture of the Tibia or Femur

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I declare that this thesis has been composed by me and that the work described herein has been undertaken by me personally.

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ABBREVIATIONS

ABI	Association of British Insurers
ADL	Activities of Daily Living
A&E	Accident and Emergency
AMAS	Activity Matching Ability System
AO	Arbeifsgemeinshaft fir Osteosynthesepragen
AP	Antero-posterior
BMDP	Bio-Medical Data Processing
BMA	British Medical Association
BMJ	British Medical Journal
BSC	British Steel Corporation
CI	Confidence Interval
DCP	Dynamic Compression Plate
df	Degrees of Freedom
EMG	Electromyography
FES	Fat Embolism Syndrome
GA	General Anaesthetic
GHAS	General Handicapped Attitude Scale
GHQ	General Health Questionnaire
GK	Grosse and Kempf
GP	General Practitioner
HLC	Health Locus of Control
ICD	International Classification of Diseases
ICIDH	International Classification of Impairments, Disabilities and Handicaps
I-E	Internal-External
IQ	Intelligence Quotient
JBJS	Journal of Bone and Joint Surgery
LHB	Lothian Health Board
MPLR	Maximum Partial Likelihood Ratio
MRC	Medical Research Council
N/A	Not Applicable
NHS	National Health Service
NOS	Neck of Shaft
NS	Not Statistically Significant
OPCS	Office of Population Censuses and Surveys
p	Statistical Probability
POP	Plaster of Paris
PTB	Patella Tendon Bearing
RIE	Royal Infirmary of Edinburgh
RTA	Road Traffic Accident
S	Statistically Significant
SD	Standard Deviation
SE	Standard Error
SHHD	Scottish Home and Health Department
SPSSX	Statistical Package for the Social Sciences
WHO	World Health Organisation
$\bar{x}$	Mean Value
YTS	Youth Training Scheme

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ABSTRACT

The lack of scientific research into the treatment of fractures, in general, was noted by orthopaedic surgeons some ten years ago and is of particular importance in the study of lower limb fracture because it is acknowledged as one of the most opinionated and contentious fields of orthopaedic practice. Therefore, in 1984, a study of this patient population was initiated at the instigation of members of the Department of Orthopaedic Surgery within the University of Edinburgh.

Following a review of the literature, it became apparent that there was no standard way of monitoring or measuring outcome following fracture. Many of the commonly used clinical instruments, such as time to union, complication rates and the incidence of malunion, were based upon subjective judgements that had not been adequately tested in terms of their properties of measurement, while the descriptive data in scientific literature on this subject was found to be contradictory. Thus, in response to these findings, a longitudinal study was planned with three objectives in view. Firstly, the intention was to standardise, test and select instruments that could be used to measure different clinical and rehabilitative aspects of recovery following lower limb injury. Secondly, the patient population was to be described in greater detail than had been attempted hitherto in order to provide sound empirically derived data to assist with the design and planning of future clinical trials. Finally, *post hoc* analyses were to be conducted in order to determine the prognostic potential of various factors thought to influence recovery upon different types of outcome.

The fieldwork for this longitudinal study took place between June 1985 and May 1987 and during this time a series of 112 patients, admitted to the Royal Infirmary of Edinburgh, were recruited to the study. Subjects were followed-up over a nine month period with each subject being interviewed on three specific occassions. Five computer compatible coding schedules were used to collect the data which comprised clinical, socio-economic psychological and functional variables.

As a result of this study, a methodology has been specified and research instruments have been designed and tested for the future evaluation of fracture treatments. Three measures have been identified which were sufficiently sensitive, valid and reliable to measure outcome following lower limb fracture. Furthermore, suggestions have been made as to the possible research design and type of statistical analyses which might be employed in the context of an experimental study.

Four main recommendations have been made for the development of clinical research in this area of interest, namely: (1) that immediate attention be given to improving and testing **clinical** and **radiological** measures of union; (2) that a large scale survey of the natural healing process should be undertaken; (3) that a clinical trial be conducted to evaluate the benefit of conservative versus operative procedures for stabilising tibial shaft fractures; and (4) that serious consideration be given to developing the appropriate resources and expertise necessary to conduct clinical orthopaedic research based on the methods of the social and behavioural sciences as well as those of the basic biological sciences.

CHAPTER 1

TIBIAL AND FEMORAL SHAFT FRACTURES

1.1. Background to the Study

Modern fracture treatment began to develop around the turn of the present century following the introduction of antiseptic surgery in 1867 and the discovery of x-rays in 1875. However, despite impressive advances in the basic medical sciences, there remains some question as to whether the **treatment** of fractures has developed into a precise science (Crawford-Adams, 1983) or whether Leake accurately described orthopaedic practice when he stated that surgery was "a great technical art" (Thompson, 1942).

Over the years, medical science has done much to explain the physiological processes at work in fracture healing and the mechanical, circulatory and biochemical conditions under which union prevails. This knowledge (based upon controlled, laboratory experimentation) has contributed greatly to the theoretical foundations underpinning current fracture treatment, but the treatment methods themselves have not come under much scientific scrutiny.

Hence, there exists a gulf of knowledge between the laboratory and the clinic which would appear to persist because the treatment of a fracture is based on clinical judgement while medical science is modelled predominantly upon methods adopted by the basic sciences.

Empirically, a person with a fractured leg is less interested in the healing process *per se* than the way the event affects his life in general. Unfortunately, scant attention has been paid to this complementary and important aspect of fracture treatment because it is much more difficult to investigate and because there are few recognised means for assessing the effects of treatment upon the person as opposed to the biological process. Nevertheless, it is arguable whether there is a need to know more about the human aspect of fracture treatment in order to select and test appropriate instruments which could be used to establish important stages of recovery following lower limb fracture.

With this in mind, the work reported in this thesis describes a prospective study of the recovery made by a series of 112 orthopaedic patients who sustained a diaphyseal fracture of their tibia or femur. The study was initiated because of the need to standardise and evaluate research instruments capable of measuring outcome in future clinical experimental research. The paucity of scientific research in the treatment of fractures, in general, was noted by White (1975), but is of particular importance in the study of lower limb fracture because Ellis (1964) considered it one of the most opinionated and contentious fields of orthopaedic practice. It is also one of considerable clinical, human and economic concern to patients, their families, their employers, the insurance industry and to the National Health Service (NHS).

1.2. Clinical Debate about Fracture Treatment

When a person breaks his leg he experiences a sudden and total disruption to his life. Instantly, he is rendered immobile and unable to weight bear. Functionally, he is no longer capable of performing all his usual social, occupational and recreational activities. While the experience of a fracture may be catastrophic to the immediate lifestyle of the person, Lee (1979) described tibial fractures as minor fractures and Ellis (1964), Karlstrom (1974) and White (1975) have stated that such fractures are common. This may account for the popularly held belief that a lower limb fracture, whilst resulting in a period of temporary disablement(1)*, generally has a favourable prognosis with little or no serious long-term consequence for the injured person.

However, there is a substantial accumulation of orthopaedic literature which has cast doubt upon the truth of these popular assertions on two counts. Firstly, since the 1940's, there has been considerable concern about the rate of fracture healing in diaphyseal fractures of both the tibia and femur (Watson-Jones et al, 1943; Ellis, 1958a; Sakellarides et al, 1964; Trueta, 1974; De Souza, 1987). The stimulus for this attention has been that a sufficiently high proportion of such fractures, seemingly, have taken an unacceptable length of time to unite. In consequence, some patients are believed to experience an unnecessarily protracted period of disability with the increased risk of their experiencing secondary limitations arising from what White (1975) has termed "fracture disease".

Secondly, there has been a concomitant and heated debate over the best method of treatment for long bone fractures. With respect to the tibia, a

* see Appendices - I Notes.

divergence of opinion exists between proponents of early, conservative treatments on the one hand (Nicoll, 1964; Sarmiento, 1967; Haines et al, 1984; Scudder, 1985; Kay et al, 1986; Sherman et al, 1986) and advocates of primary surgical intervention on the other (Muller, 1963; Zucman et al, 1970; Solheim et al, 1973; Parker, 1974; Batten et al, 1978; Bone et al, 1986). By comparison, the choice of treatment for diaphyseal fractures of the femur has always been less contentious and, since Hey-Groves pioneered the use of an intramedullary rod in 1918 and Kuntscher subsequently described his procedure of nailing in 1940, there has been a virtual consensus of opinion that early surgical intervention is justified in most cases of femoral fracture. Here, the focus of discussion concentrates upon which method of internal fixation should be selected (Steen-Jenson et al, 1977; St Pierre et al, 1982; Chan et al, 1984; Winquist et al, 1984; Kempf et al, 1985; White et al, 1986) and under what circumstances.

Yet, despite a prolific literature on the subject, the fundamental question over which is the best fracture treatment remains unanswered due to the unscientific nature of much of the published work in this field (White, 1975). The majority of articles have attempted to describe a retrospective series of patients treated with a single method of fixation (Batten et al, 1978; Chan et al, 1984; Haines et al, 1984; Winquist et al, 1984; Kempf et al, 1985; Bone et al, 1986; De Bastiani et al, 1986; Kay et al, 1986; Sherman et al, 1986; Connolly et al, 1973). Frequently, authors have adopted individualised classifications to describe the type of fracture being dealt with (Austin, 1978) and have employed subjective, non-standardised criteria (Nicoll, 1964) to report their findings. Unfortunately, and quite erroneously, authors often have attempted to draw conclusions from their results in relation to the findings of other surgeons who have favoured alternative forms of fixation, applied these to different populations of patient, under dissimilar conditions, and have used their own unique methods of assessment to report outcome. As Austin (1978) has pointed out, reports of this kind are not comparable and do nothing to resolve the controversy surrounding which is the most appropriate treatment of fractures.

More recently, the inadequacy of this type of reporting has prompted a number of authors to relate their findings from two or more treatment groups within one study (Steen Jensen et al, 1978; St Pierre et al, 1982). Once again, usually this has been undertaken retrospectively and, consequently, patients have been selected for treatment by the orthopaedist concerned, thereby creating dissimilar patient groups which effectively have comprised separate series of patients.

Some researchers have attempted to overcome this difficulty by demonstrating that these disparate groups were matched in terms of arbitrary variables such as sex, age or the "personality" of the fracture (Nicoll, 1964). Yet, no matter how interesting the data, essentially these studies are observational and any conclusions reached remain subjective.

In view of the controversy surrounding this topic, it is quite surprising that the debate has stayed at a level of descriptive rhetoric for half a century without there being any obvious attempts to investigate the efficacy of treatments using experimental research. One recent exception to this observation, published in The Lancet (Kenwright et al, 1986), set out to investigate the effect of axial micromovement upon fracture healing using a controlled, experimental design for part of the trial. Unfortunately, the authors made the mistake of combining their findings from a retrospective, non-randomised trial with those of a prospective, randomised study thus infringing the basic requirements necessary for hypothesis testing (Ferguson, 1976) and so invalidating their conclusion that micromovement will "speed up fracture healing without increasing complication rates".

Writing a decade ago about fracture treatment, one surgeon summed up the situation at that time by saying:

> "It does not appear that current clinical and experimental knowledge objectively demonstrates any particular approach to be superior. ... Additional clinical and experimental observations are necessary to provide answers to this yet unsolved problem." (White, 1975, p282)

He identified the need for ingenuity and intensive research - a need which is still unmet 10 years later - but perhaps this is not so surprising given the complex nature of the problem and the lack of appropriate instrumentation to measure clinical and rehabilitative outcome following lower limb fracture.

Before going on to consider the various clinical and rehabilitative outcome measures currently available and the problems associated with each, it is important to say something about the character of lower limb fracture and the principles and practice of fracture treatment in order to place the study in context and to justify the approach taken in this research.

1.3. Aetiology, Incidence and Character of Fractures

Tibial and femoral shaft fractures are usually sustained by active men, often around 30 years of age, who are involved in road traffic accidents or (in the case of tibial fractures) who incur sports injuries (Batten et al, 1978; Auchincloss et al, 1982; Strachan et al, 1983; Haines et al, 1984; Watson, 1985). Motorcyclists and football players are thought to be at particular risk. These relatively young, healthy individuals previously have enjoyed a degree of fitness which contrasts dramatically with the temporary disability imposed upon them following their injury. Therefore, it is of considerable importance to the patients, and in the interest of other agencies, that they are restored as quickly as possible to their former levels of involvement and performance in occupational, social, sporting and other recreational activities. Indeed, Ellis (1964) has noted the economic importance of tibial fracture simply because it occurs most often in young men thus making it worthy of further attention.

However, to justify "intensive research" efforts (White, 1975) from an economic perspective, it is not enough to argue that improved knowledge might enhance patient recovery for a few, it must also be shown that the injuries are sufficiently common to merit valuable research resources being spent on this particular topic.

1.3.1. Hospital, area and national statistics

What is the incidence of tibial and femoral shaft fractures? This question cannot be answered very readily because statistics relating specifically to lower limb diaphyseal fractures are recorded indirectly at a hospital level; while area and national statistics categorise fractures in accordance with the International Classification of Diseases - ICD (WHO, 1977). This does not distinguish shaft from certain other types of fracture(2). Nevertheless, approximate figures have been extrapolated from available data.

For practical purposes, attention has been focussed upon the incidence of fracture for people of working age (16-65 years for men and 16-60 years for women). Clinically, it was argued that children were more likely to sustain greenstick fractures of a long bone with a different prognosis from fracture in adulthood. Similarly, older people were thought more likely to sustain pathological fractures and to have different rehabilitative requirements than younger adults. For practical reasons relating to the fieldwork, 16 years was established as the lower age limit of interest because this was the age at which patients could give their own consent for inclusion in the study. The upper age limits were set to reflect the main interest in working aged people. Therefore, the following statistics relate to this particular age band.

Hospital admission statistics were obtained from the Royal Infirmary of Edinburgh (RIE) where this study took place. The RIE is a large (974 beds) general hospital situated in the centre of the city. The Accident and Emergency (A&E) department within the hospital is manned continuously and orthopaedic patients requiring immediate admission to hospital are admitted directly from the A&E department to one of three orthopaedic wards. In 1984, the year preceding this study, 2,999 patients were admitted to the orthopaedic wards at the RIE (the majority being admitted as emergency cases). Of this number, 198 had sustained a tibial shaft fracture as their primary injury; while 99 people had sustained a femoral shaft fracture. In other words, 1:15 of all orthopaedic admissions to the RIE during 1984 were due to diaphyseal fractures of the tibia; while 1:30 were due to diaphyseal fractures of the femur. There is evidence to suggest that these figures are stable over time. For example, McQueen(3) has reported that 3,000 patients were admitted to the RIE with a tibial shaft fracture between 1963-1983 (ie approximately 150 per year). In 1986, the year following recruitment of patients to this study, 178 out of 3,267 admissions (or 1:18) were due to a tibial shaft fracture.

Figures(4) available for the Lothian Health Board (LHB) area, which includes the RIE, and for the whole of Scotland for 1985 (roughly equating to the period of study) relate to hospital discharges. During 1985 some 212 people with a primary diagnosis of tibial shaft fracture were discharged from hospitals in the area; while 60 people were discharged following femoral shaft fracture. Since these statistics approximate the annual figures available for the RIE (which have been shown to be fairly constant) it would appear that, either the RIE figures account for the majority of cases of tibial and femoral fracture in the area, or that the area figures under-represent the actual size of the problem. Bearing this in mind, data available for Scotland for 1985 suggested that some 1,393 people were discharged from Scottish hospitals with a tibial shaft fracture during this period; while 510 people similarly were discharged following femoral shaft fracture.

It may be seen from these figures that tibial and femoral shaft fractures are certainly not rare occurrences and are sufficiently common to have provoked a wealth of literature on the subject. Tibial shaft fractures are relatively more common than femoral shaft fractures and together such injuries account for 1:10 admissions to the RIE orthopaedic wards where this study was conducted. Because of the greater incidence of tibial shaft fracture and the particular controversy surrounding its treatment, much of this study concentrates upon issues raised in relation to tibial shaft fractures. However, many of the points made are equally pertinent to similar fractures of the femur and this is particularly true for the classification of diaphyseal fractures.

1.3.2. The classification of diaphyseal fractures

The classification of tibial shaft fractures has been linked inextricably to those characteristics which are believed to predispose it to "delayed" or "non-union". These terms will be defined and discussed later (see Chapter 2). It is sufficient to note here that different types of fracture are thought to heal at different rates. Therefore, it is widely acknowledged and emphatically stated by Nicoll (1964) that the "personality" of a fracture must be taken into account at the outset of treatment because different fractures have a different "inherent propensity to union". A difficulty arises because there is no agreed system of classification. Researchers tend to adopt their own personal typologies which range from simple ratings on a single dimension to multivariate classifications comprising several variables within one scale. Common errors shared by all these systems are that they are usually ill-defined, often have confused rather than simplified description and rarely have facilitated comparison (Austin, 1978).

For example, the ICD (WHO, 1977) mentioned earlier is an example of a widely employed, but very gross system of classification used to collect demographic statistics. Fractures of the femoral and tibial shaft are recorded using a four-point digit code (Table 1).

Table 1: ICD Classification of Tibial and Femoral Shaft Fractures

Code	Description	
821	<u>Fracture of other and unspecified parts of femur</u>	
821.0	*Shaft or unspecified part, closed*	
	Thigh	Upper leg
821.1	*Shaft or unspecified part, open*	
821.2	*Lower end, closed*	
	Condyle	Epiphysis, lower
	Distal end	
821.3	*Lower end, open*	
823	<u>Fracture of tibia and fibula</u>	
	Excludes: Dupuytren's fracture	
	ankle	
	radius	
	Pott's fracture	
823.0	*Upper end or unspecified part, closed*	
	Head	Tibia:
	Lower leg NOS	condyles
	Proximal end	tuberosity
832.1	*Upper end or unspecified part, open*	
823.2	*Shaft, closed*	
823.3	*Shaft, open*	

Whilst this system of classification is probably adequate for administrative purposes, it is dubious whether the ICD has clinical application since it is only capable of distinguishing open from closed fractures.

Apart from the presence of a compound injury, the displacement of the fragments and the comminution of the bone, there is immense disagreement over the number and nature of other intrinsic or extrinsic factors which may affect healing. For example, Nicoll (1964) mentioned infection and fracture site (middle third fractures having a poorer prognosis) as important variables, but denied the influence of traction, age, an intact fibula, the pattern of the fracture or ethnic origin. Ellis (1958a) considered infection and distraction to be important, but neither age nor fracture site. Haines <u>et al</u> (1984) took into account the aetiology of the injury and the significance of other associated injuries. Unlike Nicoll (1964), Hutchins (1981) reported a poorer prognosis for fractures in the proximal or distal thirds of the shaft. This divergence of opinion has stimulated the development of innumerable schemes of classification, a few of which are reported here to exemplify some of the problems.

For example, Ellis (1958a) grouped fractures into three classes according to whether he considered them to be of minor, moderate or major severity. His groupings were based on an interaction between the degree of displacement, angulation, comminution and compounding present. However, he inadequately defined the terms he used, his categories were not discrete and he confounded the three dimensions under consideration (Table 2).

Table 2: Ellis' (1958a) Classification of Fractures

Class	Description
MINOR SEVERITY	Includes undisplaced/angulated fractures with or without minor comminution/compounding.
MODERATE SEVERITY	Includes completely displaced fragments with or without minor comminution/compounding.
MAJOR SEVERITY	Includes fractures with major comminution/ compounding (in practice all were completely displaced).

Nicoll (1964) devised a more systematic classification to control for the effects of displacement, comminution and compounding in his study. Each variable was rated on a simple binomial scale of severity and was then combined with every other sub-class to create eight fracture types (Table 3).

Nicoll's classification offered the distinct advantage that the effect of each variable could be investigated independently of the others. Nevertheless, there were still no definitions provided for the precise meaning of "nil/slight" and "moderate/severe".

Table 3: Nicoll's (1964) Classification of Fractures

Class	Degree of Displacement	Degree of Comminution	Degree of Compounding
1	N	N	N
2	N	N	S
3	N	S	N
4	S	N	N
5	N	S	S
6	S	N	S
7	S	S	N
8	S	S	S

where N = nil/slight
S = moderate/severe

Kay et al (1986) followed a sophisticated classification described by Edwards which grouped fractures on the basis of four dimensions, each sub-divided into three or four sub-classes and then hierarchically organised so that every possible combination of factor could be explored (Table 4). Precise definitions were given to aid the reader. The classification resulted in no less than 108 classes of fracture and, given that Kay et al (1986) had only 79 subjects in their study, the classification served little purpose and could only do so when dealing with extremely large numbers of subjects.

Table 4: Kay et al's (1986) Classification of Fractures (after Edwards).

Class	Sub-class	
1. Pattern of fracture	1.1 transverse	
	1.2 comminuted	
	1.3 oblique	
2. Displacement	2.1 none	
	2.2 moderate	
	2.3 marked	3 x 3 x 4 x 3
3. Compounding	3.1 insignificant	categories
	3.2 small	
	3.3 large	
	3.4 major	
4. Site	4.1 proximal third	
	4.2 middle third	
	4.3 distal third	

So far, these three examples classified fractures according to factors inherent to the injury itself. Hammer (1985b) adopted a different approach and classified his series into seven aetiological groups, three patterns of fracture and two groups relating to the magnitude of energy on impact. Each dimension was treated independently. Similarly, other authors have adopted unidimensional classifications. Winquist and Hansen (1980) described a classification of fractures according to the degree of comminution present and Gustilo and Anderson (1976) devised a system for classifying open fractures.

Considering the diversity of approach represented in the forementioned examples of classification, it is hardly surprising that Austin (1978) concluded that retrospective audit was not possible "owing to the dissimilarities in classification and presentation" of published material. However, little progress is likely to be made, even with prospective studies, until agreement is reached on an appropriate way of classifying fractures. This requires urgent attention because:

> "No investigation of other variables or comparison of results of different techniques of treatment can be considered valid unless the severity of the initial injury is taken into consideration." (Ellis, 1958a, p45)

It is likely that the natural history of healing for many thousands of cases of fracture will need to be documented before a comprehensive classification of fractures can be agreed which has universal applicability. Only then can comparative and clinical studies be undertaken which have the general approval of orthopaedics surgeons because they attempt to control for all extraneous variables which might otherwise influence outcome. Until such time, any conclusion reached through clinical trials will remain controversial.

1.4. Principles and Practice of Treatment

Most fractures are capable of healing in the natural state without human assistance (McKibbin, 1978) and so it is important that intervention of any kind is attempted only when there are perceived benefits to be derived from interfering with nature. Scudder (1985), for example, argued that surgical intervention was only appropriate when other methods failed – his ideal being to achieve union "without deformity and without impairment of function to the limb, either immediately or remotely". This view was shared by Weller (1983) who qualified his opinion by stating that the disadvantages of conservative treatment, used incorrectly, might also result in serious disruption to the natural healing process and detract from the quality of the final result.

Furthermore, it has been pointed out that the orthopaedic surgeon can only create conditions conducive to union, he can not accelerate healing. All he can do is attempt to ensure that the bony surfaces are placed in proximity and retain their position while union takes place (Ellis, 1958b). So, it is evident that, whilst the healing process may be disturbed by factors, including inappropriate or inexpert procedures, it can only be facilitated and not actively promoted by skilled intervention. Hence, the overriding arguments for treatment are: to position the fragments, to hold them in place, to do so without prejudicing the future functioning of the limb and to accomplish this with minimal disruption to the patient's life.

To this end, Crawford Adams (1983) has outlined three fundamental principles of fracture treatment following the initial management of the injured patient. These are:-

- reduction
- immobilisation
- preservation of function

A fracture is "reduced" only when, in the opinion of the attendant surgeon, the ends of the bone fragments are displaced sufficiently to require manipulation in order to bring them into better alignment. In cases where this is deemed necessary, a perfect anatomical position is rarely achieved or even sought. Imperfect apposition of the bone ends is more readily accepted than imperfect axial alignment because angulation is believed to have a more detrimental effect upon joint function and is believed to hamper union (Watson-Jones et al, 1943). However, what is acceptable to one orthopaedic surgeon may not be so to another and, thus, what constitutes an adequate reduction will vary from centre to centre and between different surgeons.

Basically, fractures are reduced by one of three means - closed manipulation, with or without an anaesthetic; mechanical traction, with or without manipulation and/or anaesthetic; or open reduction. Closed manipulation is achieved by manually grasping the bone fragments through the soft tissues and moving them until they are in as good a position as possible. For obvious reasons, this procedure is usually carried out under a general anaesthetic (GA), but sometimes a local or regional anaesthetic may be administered. Occasionally manipulation is carried out without an anaesthetic.

In cases where manual exertion would be inadequate to reposition the bony fragments, mechanical traction is used instead. This applies especially to fractures of the femur where the protective spasm of the thigh muscles tends to exert a strong compressional force on the fragments frequently resulting in them overriding. In this situation, traction is applied either by a weight and pulley system or by a screw device and may be achieved rapidly under anaesthesia or over a prolonged period without anaesthesia.

When all else fails, or sometimes as the method of choice, a fracture is surgically exposed and reduced under direct vision. Under these circumstances, the surgeon often will fix the fragments internally to ensure that they are firmly held in position.

Once the position of the fragments is felt to be acceptable, the fracture is then immobilised in order to prevent subsequent displacement and so minimise movements which might interfere with union or create pain.

Again, not all fractures require immobilisation, but fractures of the major long bones, such as the tibia and femur, usually do. From Table 5, it may be seen that there are four basic approaches to immobilisation, namely: external splintage, continuous traction, external fixation, or internal fixation.

Table 5: Typology of Immobilisation Techniques

Method of Immobilisation	Examples
1. External splintage (minimal intervention)	casts (plaster of Paris - POP, splints, orthoplast etc) cast/functional braces
2. Continuous traction (maximal immobilisation)	Thomas splint (with or without Pearson's knee flexion device) Braun's frame Povey splint
3. External fixation (minimal surgical intervention)	POP and Steinmann pin, unilateral bars double bars
4. Internal fixation (maximal surgical intervention)	transfixion screws cerclage wire/bands nails plates (eg AO, DCP) bone grafts intramedullary rods (eg Kuntscher, GK, Booker-Willis)

External splintage, as the name suggests, entails encasing the limb in a cast, splint or brace exterior to the soft tissues which acts as a support or scaffold for the broken bone. Most splints of this kind are intended to work on the principle of three-point fixation (Ross, 1984) and frequently require the joint above and below the fracture to be held stationary, or to be limited to a particular range of movement. Such methods of immobilisation represent the minimum degree of intervention whilst artificially attempting to stabilise the fracture site. For this reason, methods of external splintage are often referred to as "conservative" treatments. Tibial shaft fractures frequently are treated conservatively in a full length plaster-of-Paris (POP) cast which is later changed to a shorter, patella tendon bearing (PTB) cast.

Some fractures, notably femoral shaft fractures, are difficult or impossible to stabilise in an external splint alone and require the pull of the muscles to be counteracted by continuous traction to prevent overlapping of the fragments. In the case of the femur, skeletal traction is applied by the application of a weight attached to a pulley system acting upon a pin driven through the upper end of the tibia. Clearly, this system of immobilisation necessitates that the patient remains in bed throughout the period of treatment.

Forms of external fixation anchor the bone fragments to an external cast or metal bar (or bars) through the medium of pins inserted into the fragments above and below the fracture site and clamped or cemented to the external support. External fixation is used primarily for the management of open or infected fractures and, whilst the fixator is cumbersome, it interferes minimally with the mobility of the joints above and below the fracture site.

Internal fixation is selected when a fracture must be rigidly immobilised for whatever reason and entails the surgical securing of the bone fragments either directly at the fracture site or by introducing a nail or rod into the medullary cavity of a long bone through a site proximal to the fracture. Open internal fixation, that is to say techniques which expose the fracture site directly, depend upon the application of screws, nails, plates, wires or bands to the exterior surface of the bone; while, so called, "closed" intramedullary nailing describes the surgical technique whereby a metal rod or nail is inserted into the medullary cavity of a long bone without exposing the fracture site. Intramedullary nailing is an increasingly popular method for immobilising the femur (Rokkanen et al, 1969; Winquist et al, 1984; Dugas et al, 1985; Bone et al, 1986; White et al, 1986) because it avoids having to keep patients in hospital for months on end in order to stabilise the fracture conservatively (by continuous traction). Furthermore, it is claimed to minimise the risks associated with open surgery.

In accordance with his third principle of treatment, that of preserving function, Crawford-Adams (1983) has stated that rehabilitation is always an essential component of fracture treatment both in order to maximise function whilst healing is in progress and to restore function to normal once the fracture has united.

The means by which this ideal should be achieved is said to be through the encouragement of active use of the limb from an early stage, by the continuance of normal activities, as far as is practicable, and by the practise of active exercises to maintain muscle function in the immobilised limb. However, although Crawford-Adams (1983) advocates that every adult with a major fracture should attend supervised exercise classes throughout their recovery, it is debatable whether this is either necessary or beneficial for the majority of patients. Little is known about the incidence or persistence of disability post-fracture or the potential efficacy of physiotherapy treatment.

For a more adequate description and discussion about the principles of treatment and treatment alternatives the reader is referred to Karlstrom (1974), White (1975) and Crawford-Adams (1983). The purposes of briefly describing here the various treatment methods currently employed by orthopaedic surgeons are to demonstrate the wide combination of choices available and to emphasize that, although there are thought to be indications for particular techniques under particular circumstances (for example, external fixation is often preferred in cases of severe compounding), reports on the treatment of fractures by all these methods are contradictory and inconclusive (White, 1975). They also focus upon methods of immobilisation rather than reduction or rehabilitation.

The fact of the matter is that there are no clear indications as to what constitutes an acceptable reduction of a fracture. The selection of the "best" method of immobilisation is largely a matter of professional preference and the prescription of exercise post-fracture is arbitrary and its effectiveness is unknown.

In summary, there is much which is still unknown about the practice of treatment and, so, in the words of Perkin:

> "The doctor can not make a bone unite and it is rare that he can ever assist union, although he can, and often does, prevent union." (Trueta, 1978, p24)

Perhaps this remark is unjustly cynical simply because so little is known about clinical, behavioural and environmental influences upon fracture healing. Therefore, it is more accurate to state that no method of fracture treatment is of proven benefit, but equally there are no grounds to support Perkin's viewpoint that certain forms of intervention may actually prevent union.

The concept of "union" as an event rather than a process will be discussed more fully in the next chapter (see Chapter 2) and has been central to the debate concerning the choice of treatments because emphasis has been placed upon the time it takes for a fracture to unite. In reality this depends upon the operational definitions used by each clinician and the level of caution applied when declaring a fracture united (as demonstrated by one patient included in this study who was retained in a POP cast for two months after he was told that his fracture had united). Yet, despite the dubious precision of decisions relating to union - and authoritative statements of the kind made by Perkin and others (Watson-Jones et al, 1943; Ellis, 1964) that the healing process cannot be accelerated - it would appear that a fourth principle of treatment is beginning to emerge from the literature, namely, serious attempts to hasten the healing process (particularly in cases of "delayed" or "non-union").

There is a growing literature which deals with the potential of behavioural, invasive and non-invasive techniques for stimulating healing. For example, there has been much discussion about the advantages and disadvantages of early weight bearing in terms of speeding fracture healing (Brown et al, 1969; Connolly et al, 1973; Dehne, 1974). Secondary treatments have been undertaken to promote healing in cases where it is said to be slow and these include the use of bone grafts (Souter, 1969), the use of various types of internal fixation with or without the application of continuous compression (Parker, 1974; Hicks, 1977; Thompson et al, 1977; Batten et al, 1978) and techniques of external fixation which apply axial loading with cyclical compression (De Bastiani et al, 1986; Evans, 1986). There have also been attempts to excite union using electrical stimulation (Lavine et al, 1987) including direct current (Hicks, 1986) and electro-magnetic induction (De Haas et al, 1986). Finally, the potential of micromovement (Goodship et al, 1985; Kenwright et al, 1986) and chemical forms of inducement(5) are being explored in relation to the healing of bone.

1.5. Conclusion

Undoubtedly, considerable benefit could be derived from an ability to stimulate fracture healing. Needless to say, currently there is no way of knowing what might have happened had the intervention not taken place. Just because a fracture proceeds to union following, for example, a bone graft, it cannot be assumed that the treatment alone is responsible (Ellis, 1956). Causal relationships may only be established by controlled trials(6). Alternatively, the efficacy of treatments could be examined with respect to normative data on fracture healing times for different "classes" of fracture, but no such data exists. Clearly, the notion of being able to influence or accelerate union (while minimising the risk of complications such as infection or movement at the fracture site) must be set against some comparator. The next chapter, Chapter 2, discusses whether "time to union" is an appropriate measure and critically examines this and other clinical and rehabilitative dependent variables which have been used to assess outcome following lower limb fracture.

CHAPTER 2

OUTCOME FOLLOWING FRACTURE

2.1. Introduction

In a clinical setting, outcome following a fracture is assessed subjectively by experienced clinicians who make judgements about individual cases in the light of knowledge they have acquired during their training and subsequent specialisation. Such knowledge is gained through methods of authority, rationale, intuition and science (Pagano, 1981); science being distinguished from the other three by its reliance upon objective methods of assessment. However, in the context of a busy clinic, it is not always possible, or practicable, to measure every aspect of recovery in an objective way. Hence, subjective impressions of outcome are noted most frequently in patient records.

In contrast, scientific research demands that all measurements are taken and recorded with the utmost precision and so instruments must be selected on the basis of their known properties of measurement. Since these issues are raised very infrequently in relation to fracture patients, they will be discussed briefly prior to examining some of the more common measures used by orthopaedic surgeons and rehabilitation professionals. Therefore, this chapter has been divided into three major sections. The first section summarises the required properties of measurement instruments. The second, and largest, section considers the main clinical measures of outcome dwelling particularly on the importance placed upon union. Finally, the third section deals with selected rehabilitation measures of outcome which might have potential use in this area.

2.2. Properties of Measurement Instruments

In science, a variable is any property or characteristic of an event, object or person which may have different values at different times depending on the prevailing conditions. Variables which are manipulated or might affect a change are called independent variables (eg treatment method) while variables in which changes are sought are called dependent variables (eg union). It is the dependent variable which is measured by the so called "outcome measure" (eg time to union) and may either report qualitative or quantitative change.

2.2.1. Levels of quantification

Clinical and radiological tests of union are examples of qualitative measures, whilst quantitative measures assign numerical values to outcome. However, not all numerical values can be treated in the same way since there are four distinct levels of quantification which must be analysed using different statistical techniques. These four levels of quantification are:

- nominal
- ordinal
- interval
- ratio

Nominal quantification offers nothing more than a means to identify differences between groups on the basis of frequencies or counts - for example, recording the frequency of types of injury using the ICD (see Table 1, Chapter 1) would provide nominal data. The categories distinguish between different types of injury, but say nothing about the relationship between them.

Ordinal data have the same property as nominal data in distinguishing types, but classes are ordered or ranked into a scale of magnitude. Ellis' (1958a) severity of injury classification (see Table 2, Chapter 1) provides descriptive ordinal data. Minor fractures are less severe than moderate fractures using his criteria, but despite the ability to number this type of scale (eg minor = 1, moderate = 2, severe = 3) there is no justification in assuming that increments between the classes are equal. For example, one is half of two, but minor is not half moderate and the increment between minor and moderate may not be equivalent to that between moderate and severe.

It should be noted that numbering used in the context of nominal or ordinal level data can not be treated as "true" numbers and, therefore, score totals or percentages across classes are misleading. Statistically, these two levels of measurement are analysed using non-parametric tests which are designed to cope with low level data (see Siegel, 1956).

Interval data have all the properties of ordinal data, but the intervals between the levels or units are equal. For example, the interval between 10–15° arc of movement is equivalent to that between 20–25°. Some weighted scales also claim to provide interval measures (eg Thurstone scales – Oppenheim, 1966), but such scales have no absolute zero.

Finally, ratio data have all the properties of interval data whilst also having an absolute zero point. This is the highest level of quantification and examples include the Kelvin scale of temperature, time, length, age and frequency. Ratios can only be performed legitimately on this level of data as can all other mathematical options usually associated with numbers (ie addition, subtraction, multiplication, division).

The importance of this discussion will become apparent later in the chapter in relation to various instruments currently used to assess outcome following fracture. One example, time to union, is based upon qualitative and ratio information, but is often converted into a simple scale by dividing the time criterion at an arbitrary cut-off point into cases of "normal" and "delayed" union. At best, this provides an ordinal scale. Ideally, researchers strive to use measurement scales of the highest order (ie ratio) but the final choice of instrument will depend upon what is to be measured (the dependent variable) and the known properties of available measurement instruments. To this end, it is more important that the instruments or outcome measures selected are sensitive and of proven validity and reliability. These qualities are fundamental to the concept of measurement and yet there is no evidence to suggest that the way in which union is assessed is sensitive, valid or reliable – indeed, there is evidence to the contrary (Watson-Jones, 1943; Jacobs et al, 1981; Hammer et al, 1985a; Hammer 1985b). Therefore, it is appropriate to introduce these terms before discussing the actual measures.

2.2.2. Sensitivity

The sensitivity of an instrument or test is its ability to measure in units which are appropriate to the changes taking place. For example, if patients are recalled every month to have an x-ray of their leg, radiological union will be measured in months, but will be insensitive to weekly changes. Attempts to estimate time to union in weeks on this basis would be scientifically unacceptable and would invalidate the test. Conversely, it would be inappropriate to take daily x-rays if the changes being monitored take weeks to appear on x-ray. In this case the technique would be inappropriately over-sensitive.

2.2.3. Validity

In the simplest case, validation examines how well a test measures what it sets out to measure. The correlation of test scores with external criteria gives a measure of test validity. There are, in fact, several ways of examining the validity of a test. Content validity is the extent to which a measure is a good sample of the factors which it claims to measure. This is essentially a subjective matter which is judged either by expert opinion or by its general appearance of "face validity". So, it might be claimed that time to union as a measure has content validity because orthopaedic surgeons judge it to be a reasonable way of monitoring fracture healing. Time to union does not have face validity in relation to reporting functional recovery.

Empirical validity is the extent to which a test or instrument relates to current (concurrent validity) or future (predictive validity) attributes of the person tested. For example, claims that quantitative radionuclide imaging (Smith et al, 1987) can predict fracture healing must be tested prospectively against a second, independent measure of fracture healing before the technique can be claimed to have predictive validity.

The third and final test of validity is known as construct validity and assesses the extent to which a measure fits into theoretical constructs which in turn link with other observable measurements. A particular theory should state predictions about relationships between constructs. If accumulated evidence about a test supports the predicted direction of these relationships then the test is shown to have construct validity.

2.2.4. Reliability

Just because a test is sensitive and valid this does not mean that it is necessarily consistent in the answers it provides. So, a good test must be shown to be reliable. Reliability is defined as the degree to which two separate, independent measurements of the same thing agree with one another and is usually expressed by a co-efficient of correlation representing the relationship between the two sets of measurements. Like validity, there are different forms of reliability testing.

Inter-rater reliability is the extent to which administration of the same test by two or more people yields the same result. Both clinical and radiological assessment of fracture union has equivocal inter-rater reliability. Faced with the same patients and set of x-rays, it is unlikely that different surgeons would agree completely in their judgements about the state of union for different fractures. The inter-rater reliability of a test should be known if the results collected by two or more raters are to be compared. Moreover, a test must yield the same results even when applied on two or more occasions by the same rater. This quality should never be assumed. Intra-rater or test-retest reliability is a measure of the stability of the test over time.

A third type of reliability testing known as internal consistency can be applied to indices, scales or questionnaires which incorporate several responses in the same test. Half the test is correlated with the remaining half either by dividing the test in two and testing the first against the second part (split half consistency), or by correlating alternate responses (odd-even consistency).

A fourth type of reliability, equivalent forms reliability involves constructing two forms of the same test and correlating these to give a co-efficient of equivalence. Internal consistency and equivalent forms reliability are less frequently tested and are not always possible or appropriate to calculate. However, it is essential that outcome measures should be known to be stable over time and, preferably, consistent between raters.

For a more comprehensive discussion of measurement concepts see Guilford (1956), Orenstein (1978) or Pagano (1981). The sensitivity, validity and reliability of the more common clinical and rehabilitation measures will be considered in the next two sections of this chapter.

2.3. Clinical Measures of Outcome

Following a fractured leg, a person is monitored usually for many months as an out-patient attending fracture clinic - but what is the doctor looking for at each attendance? It would appear from documented studies that there are three main reasons for monitoring fracture healing. Firstly, the doctor is looking for clinical and radiological signs of bone healing which forecast the point in time when he can state that the fracture has "united". Meanwhile, he is watching for signs of any complications which might impede the healing process or adversely affect the quality of the end result. Finally, he is concerned to prevent and alleviate limiting conditions (eg joint stiffness) which might arise from the injury itself or from subsequent treatment of the fracture.

These three interests - speed of healing, complication rates and the incidence of limitations and deformity - are the most commonly reported dependent variables recorded in the results sections of articles (eg Batten et al, 1978; Nicoll, 1964; Winquist et al, 1984; Bone et al, 1986; Kay et al, 1986; White et al, 1986). Yet, without exception, these same reports have not described the means by which they collected their data, nor have they mentioned whether their mechanisms for measuring were sensitive, valid or reliable. Credibility can only be given to the results of a study which has provided evidence to support the fact that the data were collected in a rigorous, scientific manner and, therefore, these three commonly used clinical measures require closer scrutiny.

2.3.1. Union

Fracture healing is an ongoing **process** which starts as soon as a bone is broken and, providing conditions are favourable, continues through various stages of healing until the bone is said to be consolidated. The stages in this process have been described elsewhere (Urist, 1943; McKibbins, 1978; Crawford-Adams, 1983), but it is important to note that the pattern of healing is not uniform for all bones, between individuals, nor in all circumstances.

The tibia and femur are tubular bones and healing proceeds through five stages, several of which may occur simultaneously in different parts of the same fracture. These five stages are:-

- stage of haematoma
- stage of subperiosteal and endosteal cellular proliferation
- stage of callus (first visible sign of healing on the x-ray)

- stage of consolidation (union confirmed)
- stage of remodelling

Healing is not uniform throughout the fracture site. Different parts of a single fracture unite at different rates and hence the overall time taken for a fracture to heal is so variable that it is hard to say when the entire fracture has united. The process is continuous and not a discrete event which can be pinned down to a particular date. Thus, Watson-Jones (1943) concluded that it is not sensible to refer to a fixed time period for union. He stated that only a minimal period can be set. Despite this observation, long bones are said to take three to four months to unite by some authors (eg Crawford-Adams, 1983) and up to six months by others (eg Nicoll, 1964).

Watson-Jones (1943) further stated that it was meaningless to refer to an "average" period for union. Yet, mean time to union frequently is used as the basis for comparisons between different series of patients. Over and above the objections raised earlier in relation to comparing different populations of patient (see Chapter 1), there is some doubt as to whether recording union as an event, which has or has not occurred by some arbitrary point in time, is a sensitive or valid way of monitoring recovery.

An alternative suggestion was put forward by Austin (1978) who demonstrated the value of plotting cumulative percentage curves to represent healing time. His analysis of six separate studies suggested that only 50% of fractures had healed 16 weeks after injury while approximately 80% had healed by 26 weeks. This finding implies that there may be good reason for compiling a database on the natural history of fracture healing based upon information for a large number of cases of fracture. From such data it would be possible to construct a more accurate picture of different types of recovery curve under different conditions. The disadvantage of setting up such a database would be that it would require sufficient data to cover all aspects of the phenomenon being studied (Hiorns et al, 1979). Some of the many variables which might affect recovery following fracture have been noted already. Nonetheless, this has not inhibited others from attempting similar exercises. For example, Partridge et al (1987) have begun compiling a database in order to establish natural recovery curves for patients following stroke. Perhaps there is justification for doing the same and monitoring people recovering from fractures?

2.3.1.1. Delayed Union

Since at present there is no agreement over what constitutes "average" time to union (if indeed this is a valid concept), there cannot be an absolute time beyond which fractures are said to be in a state of "delayed" union. Not surprisingly, reports of the incidence of "delayed" union fluctuate considerably between studies and examples range from 11.5% (Auchincloss et al, 1982) to 43% (Strachan et al, 1983) for all types of tibial shaft fracture and 40% (Jacobs et al, 1981) to 57% (Hutchins, 1981) for more "severe" fractures.

These results are consistent with using the median as the dividing point between what is defined "normal" and what is defined "delayed" since, by definition, 50% of fractures will take longer to heal than the average. It is suggested that the term "delayed" union is a misnomer because delay is relative to the operational definition being used which might bear little relationship to the normal range of healing times displayed in the population. Simply by changing the threshold between what constitutes "normal" and "delayed" union one can change the size of the problem. For instance, if Austin's (1978) analysis was correct and 80% of all fractures heal in approximately 26 weeks, why should a cut-off point be set at 16 weeks when only 50% of fractures unite by this time? Would it not be reasonable to revise the definition of "normal" union to encompass the majority of fractures and so reflect a wider range of normality?

By contrast, the incidence of non-union is not time-dependent, but can be diagnosed radiologically from the dense appearance of the bone ends at the fracture site which appear rounded and uniformly well-defined. Consequently, the reported incidence of non-union is less variable ranging from nil (Auchincloss et al, 1982) to about 6% (Ellis, 1958a; Hutchin, 1981; Haines et al, 1984). Non-union is a term used to describe an indolent fracture which is unlikely to unite without some form of intervention. The incidence of non-union is reported as a complication of healing (see Complication rates).

2.3.1.2. Tests of Union

The decision whether a fracture has soundly united is made from a combination of clinical and radiological evidence. Clinical union is established when:-

- there is no mobility between the fragments on manual stressing.
- there is no tenderness on firm pressure over the fracture site.
- there is no pain when angulation stress is applied at the fracture site.

Some clinicians also take into account whether the person can weight bear on the unsupported limb. It is suggested that clinical testing for union should always be supported by x-ray evidence. Radiological union is established by two features appearing on x-ray:-

- visible callus must bridge the fracture and blend with both fragments.
- the continuity of bone trabeculae must appear across the fracture.

Together, these two qualitative tests and the time criterion upon which they are based constitute the outcome measure used to determine whether or not, and when, union occurs. Both tests are highly subjective and there is sparse evidence to suggest that either approach to measurement has been adequately tested. Indeed, there are grounds to believe that both tests are inaccurate.

For example, testing for union occurs at intervals determined by the patients attendance at clinic which are not uniform for all subjects. Furthermore, x-rays are not taken at every attendance and the person's leg is not always accessible for manual testing, perhaps because it is encased in plaster. When manual examination is possible, caution on the part of the surgeon in applying forces to the fracture site will adversely affect the sensitivity of the test (Hammer et al, 1985a). Similarly, the ability to identify radiological features of union will be determined by the clarity of the film and whether or not the fragments overlap. Both tests are completely insensitive and invalid when the fracture is internally fixed.

The significance of movement at the fracture site has been questioned (Jones, 1912) and it has been shown that absence of pain is not necessarily indicative of union (Jorgensen, 1972). Equally, the validity of radiological testing has been disputed by Hammer et al (1985a) who were unable to correlate radiological assessment of union with their mechanical assessment of strength of union (confused by the fact that they refer to "validity" as "reliability"). In fact, although others eg (Brown et al, 1976) have disputed the reliability of radiological assessment, Hammer et al, (1985a) implied that their test might have had inter-rater reliability by stating that there were "only small differences in the seven radiologists' evaluations of the individual fractures." However, they did not correlate the results between the different raters, but simply made a judgement about the data.

Clearly, the weight of evidence suggests that clinical and radiological tests of union are insensitive, invalid and unreliable. Therefore, it is encouraging to note that a number of more objective methods for assessing union are being investigated including: strength of union (Hammer, 1985b); bone imaging (Stevenson et al, 1974); ultrasonics (Brown et al, 1976) resonant frequency (Cunningham et al, 1986a); osteomedulloangiography (Puranen et al, 1981); nuclear magnetic resonance (Newman et al, 1985) and tests of fracture stiffness (Cunningham et al, 1986b). However, many of these methods of testing are either invasive or require further research before they will be suitable for routine clinical use.

2.3.2. Complication rates

As an adjunct to reporting time to union, many studies also report the incidence of certain complications which have arisen at the time of injury, shortly afterwards or during the course of treatment. The incidence of non-union is one such example, but others include infection, ischaemic contracture, venostasis, gangrene and various deformities. For the purpose of this report, deformity will be dealt with under a separate heading (see Limiting Conditions and Deformity).

While undoubtedly it is useful to include any information relevant to fracture healing, by reporting complication rates authors have attempted to do more than provide descriptions - they have attempted to use these variables as measures of outcome. For example, Kempf et al (1985) tried to compare four studies on the basis of incidence rates for pulmonary embolism, fat embolism, sepsis and aseptic non-union amongst other criteria. Other authors (eg Sakellarides et al, 1964; Batten et al, 1978) have made frequent reference to the incidence of infection in different series of patients. Moreover, complication rates invariably are reported as results in scientific articles. The implicit assumption underlying the use of variables in this way is that the lower the reported incidence of complication, the more successful the method of treatment. But can this be justified? Can complication rates be used as *bona fide* methods of measurement?

The sensitivity of using complication rates as a measure of outcome depends upon the variables included under this heading and the criteria used to establish their presence or absence. As with the classification of fractures, there is no standard way for reporting complications and some authors are more comprehensive in their coverage of items than others. For example, Steen Jensen et al (1977), talking about middle third femoral fractures, distinguished between general and local post-operative complications in their series of 104 patients treated with medullary nailing or AO compression plates. They listed the general post-operative complications which they noted under the headings: cardiopulmonary, phlebothrombosis, pulmonary embolism, fat embolism, peroneal paralysis, other (gastro-intestinal, renal, cerebrovascular or haematogenous) and death. The local post-operative complications covered were: wound infection, deep infection, osteitis, unsuccessful internal fixation, failure of implant, loose screws and migration of nail. Steen Jensen and colleagues (*op cit*) reported the incidence of non-union separately.

Winquist et al (1984), writing about closed medullary nailing in 497 cases of femoral fracture and 23 cases of open medullary nailing combined clinical complications and deformity under one heading. The former items cover the incidence of infection, non-union, peroneal nerve palsy, fat embolism, pulmonary embolism and death. Since Winquist et al (1984) did not mention one instance of implant failure is it to be assumed that none occurred? In other words, are omissions in reporting specific complications indicative of trouble-free recovery or does it mean that these particular complications were not noted? Furthermore, it is important that the reader should be made aware of the way in which complications have been categorised. Clearly there is a difference between screening all patients to confirm or deny the presence of phlebothrombosis, and recording only those cases which have been diagnosed? There is also a need to specify the criteria that have been used to define each complication. Certain events such as death or amputation may appear to be unequivocal, but others such as refracture (Haines et al, 1984) or the need for a secondary operation (Kay et al, 1986) are imprecise and require further explanation.

The next question is whether or not complication rates are valid tests of successful treatment. Some complications may arise irrespective of the treatment undergone by the patient and on this basis it is reasonable to consider only secondary complications as dependent variables. Complications attributable to the injury itself must be viewed as independent or intervening variables. For example, fat embolism is a term used to denote the presence of globules of fat in the circulation and lung following fracture of a long bone and is said to arise in the vast majority of cases (Lindeque et al, 1987). Fat embolism syndrome (FES) is a more serious, but less frequent manifestation of the same phenomenon which results in various degrees of respiratory insufficiency and is sometimes fatal. Unless it can be demonstrated that the occurrence of fat embolism or FES was exacerbated by events following fracture (eg multiple attempts at reducing the fracture) the incidence of fat embolism is a clinical complication of fracture, but is not a consequence of treatment. Therefore, a distinction must be drawn between those complications which describe the presenting condition and those which result from positive or negative action following fracture and so constitute outcome measures. This distinction is not usually made, but would seriously affect the validity of tests based on complication rates.

Lastly, it cannot be assumed that the way in which data is collected in order to report complication rates is reliable. Unless explicit instructions are followed and precisely adhered to, it is unlikely that individual raters, and even the same rater over time, would produce the same results. Just because a variable such as the death of a patient records a definitive event does not mean that figures for the incidence of death following fracture will be reported consistently by different people. For example, one rater might report all deaths in the year following fracture while another might report only deaths resulting from operative intervention. The results of these two raters would produce inconsistent data. Unfortunately, these issues have not received sufficient attention in the literature despite the fact that important clinical decisions are influenced by reports of complications, particularly infection rates. Caution needs to be exercised when interpreting these results.

2.3.3. Limiting conditions and deformity

A broken bone rarely heals in perfect anatomical alignment. There are many reasons why this is so. Firstly, as already noted (see Chapter 1), when a fracture requires reduction it is rarely possible to reposition it accurately, and even if this were possible, there would be no guarantee that the fragments would remain in position. Of course, this will depend upon the method of fixation used to stabilise the fracture and is one of the arguments used in favour of employing methods of internal fixation which hold the fragments firmly in place. Alignment, in this latter case, depends upon the skills of the surgeon in apposing the bone ends. Finally, the behaviour of the individual himself will affect the quality of the end result. Too early or too vigorous weight-bearing, particularly on an externally splinted limb, may result in a soundly united, but deformed bone (De Souza, 1987).

2.3.3.1. Malunion

The term malunion is used to describe fractures which have healed in imperfect alignment. Rotational deformities result in the distal fragment being either medially or laterally rotated relative to the proximal fragment. In other words, the foot is turned in or out, respectively, relative to the leg above the fracture site. Angulation of fragments can occur about the long axis of the bone, but is most frequently noted in relation to the frontal plane. Angulations towards the mid-line of the body are termed valgus deformities while those away from the mid-line are known as varus deformities. A loss of contact between the diameters of fragments constitutes displacement which may occur in any direction about the horizontal plane. At its extreme, displacement may result in the overlapping of fragments with the result that the limb is shortened. Bowing or recurvatum in any direction has a similar shortening effect.

Malunion may be detected from clinical examination or x-ray (antero-posterior or lateral) and would appear to have face validity as a measure of deformity. However, since it is uncertain how clinicians actually quantify malunion for research purposes, the sensitivity of the measurement techniques and their reliability remain unknown. Obviously, "guesstimates" made in the context of a busy clinic are wholly inappropriate to measure outcome, but even the most specific techniques for measuring x-ray data will be prone to error and must be tested prior to use. Measurements taken from the patient's limb using surface markings to fix end points are renowned for their inaccuracy and should be treated with suspicion unless the error of measurement is known.

In general, reports have quoted measurements in degrees or centimetres (ratio scale), but have gone on to summarise details in an ordinal scale. For example, Nicoll (1964) considered anterior or posterior angulation, varus or valgus, rotational deformity and multiple deformity (occurring in two planes) as four separate variables which he scaled accordingly:-

- functionally insignificant (less than 10°)
- moderate deformity (10 - 20°)
- severe deformity (over 20°)

He then proceeded to sum the incidence of severe deformity across the four variables concluding that "severe residual deformity (over 20 degrees) occurred in only 12 cases". Unfortunately, there is no justification for adding ranked data in different ordinal scales to produce a grand scale of deformity.

In a study which attempted to compare two series of patients with femoral fractures treated with Kuntscher and AO techniques of fixation, Chan et al (1984) reported malunion in terms of rotational deformity and shortening only. Like Nicoll (1964), they tried to band their findings into an ordinal scale, but failed due to the inaccuracy of their definitions:-

- none
- less than 10°
- less than 20°
- more than 20°

Their middle two grades were ambiguous and the last two grades appear to exclude the measurement of 20° of rotation. While this might seem a trivial point to make, in practice, such ambiguity could make the difference between the scale producing reliable or unreliable data (see Chapter 3).

One final example of a scale which seriously confused classification and measurement was devised by Dencker and adopted by Steen Jensen et al (1977). Steen Jensen and colleagues described outcome following medullary nailing or AO compression plate fixation after femoral fracture. They reported the results of a follow-up study on 90 patients using data collected by questionnaire, clinic examination and x-ray examination which they then compiled into a complex scale comprising: very poor, poor, satisfactory and excellent - see Table 6).

Table 6: Steen Jensen et al's (1977) Functional Scale (after Dencker)

Result	Definition
Excellent	No complaints Shortening <3 cm Angulation <15° Knee flexion >90° Quadriceps atrophy <2 cm Full knee extention
Satisfactory	Moderate complaints Shortening <5 cm Angulation <20° Knee flexion >45° Quadriceps atrophy <3 cm Knee extention reduced <5° Knee instability <10°
Poor	Severe complaints Shortening <8 cm Angulation >20° Knee flexion <45 Quadriceps atrophy >3 cm Knee extension reduced >5° Knee instability>10°
Very poor	Very severe complaints Non-union Shortening >8 cm Thigh amputation

The authors used this tool as a measurement instrument stating that "the overall results according to Dencker's classification (1965) showed 95 per cent excellent or satisfactory results in both groups" (Steen Jensen et al, 1977, p180). In the hands of even experienced staff this tool is of dubious value because it appears insensitive and is so complex as to be likely to be unreliable. It is evident that the basic principles of classification and measurement have been misinterpreted.

In addition to malunion, different forms of immobilisation pre-empt certain sorts of limitations which can be temporary or persist for many years (Solheim, 1960). External splintage which restricts knee and/or ankle movements for months on end is said to lead to the stiffening of joints and the atrophy of muscles through inactivity (Gossman et al, 1986). In fact, regaining joint mobility and muscle strength can pose a greater problem for the person than coping with the fracture. Hence, these two limiting conditions, together with factors like the incidence of flat-foot, swelling, arthrosis (Solheim, 1960) and soft tissue calcification (Steen Jensen et al, 1977) are sometimes used as dependent variables too. In particular, the measurement of joint stiffness and muscle wasting warrant further discussion.

2.3.3.2. Joint stiffness

Unlike most of the measures discussed so far, techniques for measuring joint range of movement are well documented ranging from the simple use of line drawings (McMaster, 1976) and manual goniometric measurements (Norkin et al, 1985) to the sophistication of electrogoniometers (Brinkmann et al, 1985), torque devices (Haskard et al, 1985), and three dimensional tracking systems (Towle, 1986). Yet, whether a pen and pencil approach is adopted or whether a computerised system is employed the same fundamental principles of measurement apply.

Perhaps the most widely used instrument for measuring joint range is the goniometer, although again authors rarely mention the technique they followed to obtain their data. Goniometric measurement is renowned for being unreliable, especially between different raters (Boone et al, 1978; Pandya et al, 1985) and so, whenever this technique is employed its reliability should be tested. The sensitivity of assessing joint movement will depend upon the error of measurement associated with each technique and the way in which these measurements were then used. For example, Ellis (1958b) reported cases of knee stiffness and cases of ankle and/or foot stiffness as binomial variables. Patients either had a stiff knee or they did not, but he did not specify his criteria for determining "stiffness". Kempf et al (1985) reported regained movement in degrees, but did so without referring to a standard. They said that hip and knee movement was restored completely at six months in all but three of their patients without saying how this was established. Solheim (1960) related joint mobility to normative data. He stated that the ankle normally demonstrated 10-20° dorsiflexion and 35-40° plantarflexion and on this basis he divided subjects into those with normal mobility of the ankle and those with reduced mobility. (Sepic et al (1986) did not agree with these norms.) Like Ellis (1958b), Solheim ended up with a binomial variable of doubtful validity. Batten et al (1978) expressed ankle range as a percentage of normal and use an ordinal scale to summarise their results. Finally, McMaster (1976) expressed the range of movement of the hindfoot as a fraction of that measured in the opposite leg and created an interval scale based upon severity of limitation.

Of the examples cited above, McMaster's procedure produced the most sensitive and valid instrument because it took into account the argument that population norms should not be used when assessing return of movement due to the population variance being so great (Roaas et al, 1982) and it provided the highest level of data. However, the reliability of this procedure and the other techniques mentioned above was not reported.

2.3.3.3. Muscle weakness

Finally, as with measures of joint movement, techniques for measuring muscle strength have been well documented and range from indirect measures of muscle bulk (Parry, 1980), through ordinal scaling such as the Medical Research Council's (MRC) Oxford Scale (Coates et al, 1982), electromyography - EMG (Wolf et al, 1986) to the use of myometers (Hyde et al, 1983), Metrex machines (Cleak, 1985), Cybex (Scranton et al, 1985; Timm et al, 1985) and microcomputer systems of analysis (McLaughlin et al, 1987; Zeiderman et al, 1984).

The validity of measuring muscle bulk using circumferential measures has long been questioned because swelling counter balances wasted muscle. However, most of the other techniques are believed to be valid measures of strength, but not function. The MRC Oxford Scale is the least sensitive and most subjective of those examples given. Strength is ranked on an ordinal scale as follows:-

- 0 No contraction
- 1 Flicker or trace of contraction
- 2 Active movement with gravity eliminated
- 3 Active movement against gravity
- 4 Active movement against gravity and resistance
- 5 Normal power

As with joint range, measures of bulk or strength have been related to population norms (see Edwards, 1977; Lennmarkan, 1985) or to equivalent measures taken from the opposite limb (Parry, 1980; Coates et al, 1982). Most authors (eg Steen Jensen et al, 1977) reporting post-fracture recovery have relied upon measuring the circumference of the limb and report reductions of bulk in centimetres without reporting the reliability of their techniques or questioning whether this approach is appropriate.

2.4. Rehabilitation Measures of Outcome

As already stated, patients perceive recovery in terms of the restoration of function and the resumption of activities which they performed prior to injury and so it is befitting to consider rehabilitation measures as potentially valid means for assessing outcome following a lower limb fracture. In fact, many orthopaedic surgeons have attempted to assess functional outcome by devising their own, unique instruments, some examples of which are described later in this section (see Functional outcome). However, measurement in rehabilitation is beset with difficulties because it is such a broadly-based topic which spans the activities of many professionals and the multiple needs of patients. It is also a subject which, according to Nichols (1979), owes its scientific development to a number of arts and sciences including sociology, psychology, vocational education and medicine. Due to this diverse background, it has been estimated (Bolton, 1985) that there are over 10,000 different tests available to the social scientist - many of which are psychometric tests. This choice may seem considerable, but, in reality, it is limited by the fact that many of these existing measures were constructed for specific purposes or have minimal supporting documentation.

In the final part of this chapter, consideration will be given to a limited number of examples of socio-economic, psychological and functional measures which might have relevance to measuring outcome following lower limb fracture.

2.4.1. Socio-economic outcome

Winefield et al (1986) have suggested that chronically ill people make judgements about their recovery in terms of their resumption of pre-illness social relationships and activities. In fact, the importance of social interaction in minimising the experience of disability following illness or injury has been pointed out in relation to the concept of normalisation (Olson, 1985) which has been defined as the revaluation of a devalued person. Safilios-Rothschild (1970) has said that disabled people are devalued in our culture. Therefore, disabled individuals strive to become as normal as possible, as quickly as possible, in order to regain their former social and economic status.

Using self-report frequency scores for recording activities performed in the home, outdoors and for social interactions, Winefield et al (1985) demonstrated that during early recovery chronically ill people associated health status with their frequency of participation in outings and social activities while later on rate of participation in work, sex and exercise became more important indicators of health.

Likewise, "normality" for people with lower limb fracture is articulated in terms of returning to work (whether household or paid employment), social commitments and sports activities at a level of involvement matching that displayed prior to injury. While there are innumerable validated, reliable scales and indices to measure activities of daily living - ADL (Katz et al, 1963; Mahoney et al, 1965; Sarno et al, 1973; Granger et al, 1979; Holbrook et al, 1983; Durham et al, 1985; Jacelon, 1986), many of these are targeted at specific populations of patient - particularly older, less active people with chronically disabling conditions such as stroke or arthritis.

Obviously, ADL scales which consider ability to perform tasks such as toileting, dressing and bathing are insensitive tests of outcome for working people who play sport and drive vehicles. Because of this, Feinstein et al (1986) have drawn attention to the need to select or create activity indices that are "sensible", by which they meant that measures should fulfil the specific goals of the study. There appear to be few activity indices which satisfy this criterion for people recovering from lower limb fractures.

Other socio-economic dependent variables which have been used in studies of lower limb fracture include: return to work (Hutchins, 1981; Chan et al, 1984), length of hospital stay (Chan et al, 1984; Haines et al, 1984), and loss of earnings (Hutchins, 1981). Length of hospital stay tends to be measured in days while return to work is either recorded as yes/no or is reported in weeks. The validity of both these measures has been questioned because, as Nichols (1979) has pointed out, often the surgeon's whim or the ward sister's practice determines the length of time a person stays in hospital or remains off work. Work is a complex outcome because it is also dependent upon the type of job being undertaken. In general, the more physically demanding the work, the more advanced a person's recovery must be prior to their resuming work. Unemployment further complicates the issue.

Once again, orthopaedic articles on lower limb fractures tend not to discuss the validity and reliability of the socio-economic variables they have employed and very few studies make use of existing ADL scales in order to develop and test more appropriate activity indices.

2.4.2. Psychological outcome

Relatively speaking, the properties of psychometric tools are well tested, although psychological outcome is reputed to be under-investigated in rehabilitation research. For example, Flamer (1985) identified 34 articles appearing in one major journal of rehabilitation between 1977-1983 which reported outcome, follow-up or epidemiological study subsequent to in-patient rehabilitation centre care. Of this number, only 18 had included a psychological outcome variable despite the fact that psychological factors are acknowledged as outcome variables in their own right.

One major problem in selecting suitable psychological variables is the immense variety and high number of tests available. Of the thousands of different tests, it is difficult to choose a valid measure which will examine the anticipated outcome of a particular rehabilitation process.

From his analysis of those studies which had incorporated psychological outcome variables, Flamer (1985) clustered the types of variable under five main categories as follows:-

- internal non-enduring affective states (eg subjective reactions, satisfaction)
- enduring sense of self or cognitive structure (eg belief systems, self concept)
- global adjustment (eg psychological adaptation, personality)
- cognitive-intellectual functions (eg IQ, memory)
- behavioural (eg social contact, self management of subjective distress)
- psycho-physiological experience (eg experience of physical discomfort/pain)

Clearly, not all these types of test are appropriate to include in a study of recovery following fracture. While it may be relevant to test the IQ of a person who is recovering from a head injury, IQ testing would have little face validity in the present context. Even the psychological experience of pain, which at first would seem to be highly relevant to the current study, is of questionable value since it is arguable whether pain is an obstacle to recovery or an outcome of treatment. Certainly, the absence of pain is noted during clinical tests of fracture healing and is an important prerequisite to determining whether a fracture has united, but even the validity of this criterion has been disputed. Nevertheless, there are a number of pain scales (eg Keele, 1948) and questionnaires (eg Melzack, 1975) which have been rigorously tested and are available to the clinician, but these have been little used. (See Melzack et al, 1971; Huskisson, 1974; or Weisenberg, 1980, for a fuller discussion of the measurement of pain.)

Other psychological measures of potential use in relation to people with lower limb fractures might include measures of patient satisfaction (Levin et al, 1986) and attitudes of well-being, especially in relation to work (Warr et al, 1979).

Since work is one of the main activities disrupted when a person fractures his or her leg, it is reasonable to suppose that work attitudes might be influenced by, and might influence, the period of time people are off work.

Examples of psychological instruments designed to investigate attitudes and belief systems and which have been specifically developed, or adapted, for use by health professionals include the Health Locus of Control - HLC (Wallston et al, 1976), the General Health Questionnaire - GHQ (Goldberg, 1979), the General Handicapped Attitude Scale - GHAS (Buijk, 1986) and the Recovery Locus of Control (Partridge, 1985). Of these tests, the Recovery Locus of Control has the greatest face validity for people recovering following fracture, but it is not yet available for use. Therefore, the HLC is the only instrument identified which has been extensively tested (Snow et al, 1983; Tarrier, 1983; Lee et al, 1984) and would appear to have some relevance to injured people.

In summary, intuitively it might be felt that psychological factors have an important part to play in assessing outcome following lower limb fracture, but to date psychological tests have not been used widely for this purpose. There are no prescribed methods for selecting appropriate psychological tests for this patient group. The reader is referred to Bolton (1985) for a more detailed discussion about relevant psychological tests.

2.4.3. Functional outcome

Assessing the functional end result of fracture treatment is a difficult variable to measure, but is one which has been attempted by a number of authors who have devised their own measurement instruments. For example, in an attempt to assess outcome following tibial fracture, Batten et al (1978) devised a scoring system whereby marks were subtracted out of 10 for the presence of the following:-

- limited knee flexion
- tenderness or warmth at fracture site
- bad scar
- limited tip-toe walking
- flat hop

- any unsatisfactory sign on x-ray
- limited mid-tarsal or sub-talar movement

The resultant scores were used as a measure of the success of treatment. Subjective scores were obtained from both the patient and surgeon and these were compared and were reported as being similar. No attempt was made to compute a statistical reliability co-efficient between the two sets of scores. However, irrespective of the degree of consistency of the test, it is doubtful whether this test was sufficiently sensitive or valid to merit acceptance as a functional outcome measure - one reason being that the score combined functional activities with diagnostic signs and symptoms. The range of items considered was extremely limited and the terminology used was not defined. There were no scientific grounds for employing this global approach to measurement.

At the other extreme of detail, Nachinolcar and Vad (1985) devised a *proforma* for the functional evaluation of orthopaedically impaired, disabled and handicapped patients based upon the ICIDH (WHO, 1980). Over 100 variables were given scores on a 0-8 or 0-10 ordinal scale. The authors advised that these scores could be summated and separate percentages calculated for impairment, disability and handicap, thereby giving an overall picture of the person's abilities. Once again, there were no grounds for advocating the use of a classification as a measurement tool. The scales for each variable were ordinal and, legitimately, neither could be summed nor converted into percentage scores.

One final example of a functional assessment which might have been pertinent to this study was created by the British Orthopaedic Association Research Sub-committee. They compiled a standard chart for assessing the function of the knee before and after reconstructive operations (Aichroth et al, 1978). The chart included personal details and items relating to deformity, but also covered the following functional items:-

- ability to walk
- use of walking aids
- gait
- ability to get out of a chair
- ability to climb stairs

Ordinal scales were defined for each of these items. However, while it was noted that the chart would be controversial, no attempt was made to justify the selection of items nor to establish the scientific properties of the instrument.

Certain tests of physical fitness (Johnson et al, 1979) and exercise tolerance, such as the 12-minute walking test for assessing disability in chronic bronchitis (McGavin et al, 1976), have been evaluated in terms of their properties of measurement with respect to a person's general exercise tolerance. Yet, perhaps the most comprehensive and certainly the most well-tested tools available for evaluating the specific functional abilities of relatively active disabled people have been developed within the field of occupational assessment (Crewe et al, 1981; Jochheim et al, 1984; Wilcocks, 1979; Watson, 1987). These type of assessments have been based upon what Jochheim et al (1984) have termed "elemental abilities" - in other words, basic functions or movements such as walking uphill, bending and kneeling as opposed to ADL type tasks such as bathing, toileting and cooking. Each item is scaled according to the person's ability to perform it. So, for example, an ordinal three-point scale might consider the ability to run in terms of: normal ability, difficulty, or unable to run (Watson, 1987). The advantage of these work related assessments is that, in combination with information about job demands, they offer the basis for determining whether a person is able to perform all the physical aspects of his job and so whether he is ready to return to work. However, it is possible to apply the principles upon which these scales are based to other activities as well. (See Watson and Cornes (1986) for a more detailed discussion about techniques of occupational assessment.) At the time of writing, ability assessments of this kind had not been employed to assess functional outcome in a clinical environment.

2.5. Conclusion

There is no set way to measure outcome following a tibial or femoral shaft fracture. Conventionally, clinical measures have attempted to quantify outcome in terms of time to union, complication rates and the incidence of limitations and deformities. But, while such instruments have employed units of measurement which have given the appearance of being objective, the variables themselves have been based upon subjective, non-standardised criteria which have not been exposed to the usual rigours of scientific evaluation. That is not to imply that subjective assessment has no part to play in evaluating outcome. Indeed, in a clinical environment, it would be unrealistic to suggest that all patients should be exposed to a battery of scientific tests since this would be both time consuming and costly. Yet, in the context of scientific reporting, it is relevant to point out that the confidence placed upon the accuracy of data reported in any study is determined by the methods and procedures employed by the research team. In this respect, orthopaedic research is no different from any other type of research which strives to discover the truth about a particular situation and, certainly, rehabilitation research is subject to the same criticisms discussed to date, but applied to different concepts and methods of testing.

However, the purpose of this thesis was to focus attention upon measuring outcome following tibial and femoral fractures because these injuries have been singled out as being subjectively "difficult" types of fracture. Part of the explanation for this reputation may be due to inadequacies inherent to the measurement instruments themselves. For example, with respect to union, shortfalls in clinical and radiological tests of union have been identified already and research is underway to devise and evaluate new procedures which, quantitatively, will measure fracture healing with greater accuracy. However, equally pressing was the need to measure the qualitative end result of recovery following fracture in a way which was meaningful to both the person and clinician. Patients review their progress relative to their ability to resume activities which they performed prior to injury. While there were many tried and tested instruments available to the rehabilitation professional, few were appropriate for measuring outcome following lower limb fracture and, therefore, new instruments were required.

The purpose of this study was to examine the consistency of data gathered in order to describe and compare different series of patients with tibial or femoral shaft fractures and to assess the measurement potential of a select number of clinical and rehabilitation dependent variables which could be used to measure outcome following different methods of stabilising such fractures. The next chapter, Chapter 3, describes the methodology and procedures adopted in order to pursue these general objectives.

CHAPTER 3

METHODOLOGY AND PROCEDURE

3.1. Introduction

The study described in this and the next three chapters reports one aspect of the "Development in Rehabilitation Studies" research programme funded by the Association of British Insurers (ABI) and undertaken by the author on behalf of the Rehabilitation Studies Unit at the University of Edinburgh. Recruitment of subjects to the study was conducted at the Royal Infirmary of Edinburgh (RIE) with the permission of those Consultant Orthopaedic Surgeons who comprised the Trauma Group within the University Department of Orthopaedic Surgery between 1984 and 1987.

The ABI's willingness to support this research arose from the fact that patients' sustaining tibial and femoral shaft fractures frequently did so as the result of road traffic accidents or sports injuries (see Chapter 1.3). Because of the nature of such accidents, patients were likely to make a motor liability or personal accident claim against either a third party or their own insurance policy, respectively. Hence, research directed towards improving current awareness about the recovery made by this group (with the ultimate goal of enhancing clinical practice) not only offered the potential for benefiting all patients sustaining these injuries, but also, by doing so, indirectly promised to benefit the insurance industry by creating the most favourable conditions for their claimants, thereby containing costs which might have arisen from less favourable circumstances. So, when the ABI was approached to support this clinical research they agreed to do so.

An early ambition of clinical colleagues to combine a correlational study and experimental trial (Watson et al, 1984) was postponed owing to the need to evaluate the properties of measurement, accredited to a particular technique of bone scanning, for measuring the vascularity of bone around the fracture site. The correlational study intended to evaluate the predictive validity of this specific technique of bone scanning for identifying fractures which were to remain ununited 16 weeks and 24 weeks following fracture. The experimental trial intended to examine the efficacy of early cortico-cancellous onlay grafting, in the presence of low scan activity, to assess its potential for stimulating bone healing. However, at an early stage in the planning of this research, two factors became apparent which were to delay the start of the experimental trial. Firstly, the inter-rater reliability of the scanning technique had to be assessed before it could be used as the basis for allocating subjects into a randomised trial of early bone grafting. This was imperative since a different radiographer was to perform the scanning procedure and process the scan data than had done so for earlier investigations (Smith et al, 1987).

Secondly, in selecting and operationalising dependent variables for the study, it became evident that available instruments for measuring outcome were, themselves, untested. Because the properties of measurement for such variables were unknown, it was essential that these were examined prior to commencing the experimental trial.

The task of evaluating the inter-rater reliability of the bone scanning technique was undertaken by the University Departments of Radiology, Medical Physics and Orthopaedic Surgery. Meanwhile, the instruments and procedures devised for the original study were piloted. It was proposed that these should be used as the basis for a prospective, descriptive study of the patient population so that vital information could be collected to assist with the detailed design of the originally proposed trials and, also, to enable potential outcome measures to be identified and tested. This latter goal was essential since it became increasingly apparent that the sensitivity, validity and reliability of tests of union were in question.

The additional advantage of embarking upon a prospective, descriptive study was that it provided a unique opportunity to record comparative data, at pre-determined intervals, for each subject. Furthermore, standardised methods for collecting information could be prescribed in advance, thereby increasing the likelihood that the data would be reproducible. Hitherto, the majority of studies in this area had reported information that had been extracted solely from patient records or at a single point in time, so producing results that related to different stages of recovery for different patients. As far as the author was aware, this was the first longitudinal study of its kind to collect data, systematically, at comparable, pre-determined time intervals across a population of patients. The design of the study also took a novel approach to the measurement of outcome by including physiological, socio-economic, psychological and functional variables within the one investigation.

3.1.1. Objectives

Three specific aims were outlined for the descriptive study which were as follows:-

- to select and test instruments which could be used to measure physiological, socio-economic, psychological and functional outcome for future experimental research (eg time to union, resumption of social activities, attitude to health and return to work).

- to describe the patient population in terms of clinical, socio-economic, psychological and functional variables (eg pattern of fracture, occupation, experience of pain and ability to run).

- to perform *post hoc* testing upon those independent variables which were demonstrated to be reliable to assess their potential affect upon outcome (eg compoundness, site of fracture, pattern of fracture, infection, attitude to work, occupation, marital status and sex).

Statistical analyses were conducted with the help of the Statistical Package for the Social Sciences (SPSS, 1986) and BMDP Statistical Software (BMDP, 1985), both of which were run on the University mainframe computer, and a software package called Microstat (Ecosoft, 1984) run on the departmental Apricot Xi microcomputer. A limited number of calculations were performed manually. The descriptive statistics computed included frequency data and measures of central tendency and dispersion, where these were appropriate. Test of validity and reliability included percentage agreement or phi (Guilford, 1956) for nominal level data; Kendall's tau or Spearman's rho (Siegel, 1956) for ordinal level data and Pearson's r (Pagano, 1981) for interval and ratio level data. *Post hoc* tests of association also included the use of Chi-square (Siegel, 1956) and Survival Analysis (Armitage et al, 1987).

A result was considered to be statistically significant if its probability of occurrence by chance was 5 in 100 or less (ie $p \leqslant 0.05$). For the assessment of reliability, a criterion of 70% agreement or a correlation coefficient of 0.70 was set to distinguish between "acceptable" and "unacceptable" associations between two, independent measures of the same thing(7).

3.1.2. Access to patients

The recruitment of patients to this study took place from the orthopaedic wards at the RIE. Since the study was conducted by one Research Associate/physiotherapist, employed by the University of Edinburgh, the first step in seeking access to patients was to obtain an honorary Health Board contract for the Research Associate in order that she was able to gain access to hospital facilities.

Ethical clearance to proceed with the original study was granted by the Hospital Ethics Committee and the Trauma Group of Consultants prior to the appointment of the author. However, with the postponement of the original study, it was felt necessary to confirm the continued cooperation of the five Consultants whose patients were eligible for entry into the descriptive study. (Effectively, the alteration of plan meant that the data collection instruments and follow-up procedures were to be piloted for a protracted period of time upon a series rather than upon a limited number of subjects.)

Once this permission had been granted, visits were made to the Senior Nursing Officer, Ward Sisters, Medical Secretaries and other ward staff in order to explain the purpose of the study, to gain their support and to agree upon procedures of recruitment which would be convenient for all concerned.

Finally, having agreed a practical means for recruiting patients, the Research Associate was able to contact individual patients to obtain their signed consent to take part in the study.

This process of imparting information, seeking advice and obtaining and maintaining the co-operation of staff in contact with patients was imperitive for the success of the study. Without such co-operation, patients would not have been recruited to the study in the first instance and, therefore, the importance of this stage of negotiation can not be over-emphasized.

3.2. Subjects

Subjects were approached to participate in the study only if they fulfilled the following six criteria:-

- they had to be admitted to the orthopaedic wards at the

Royal Infirmary of Edinburgh.

- they had to have sustained a single tibial or femoral diaphyseal fracture, with no joint involvement, as their primary injury.
- they had to be of working age (or working pensioners).
- they had to have a traumatic fracture (ie patients with pathological fractures were excluded).
- they had to be resident in Central or Southern Scotland.
- they had to give their informed consent to take part in the study.

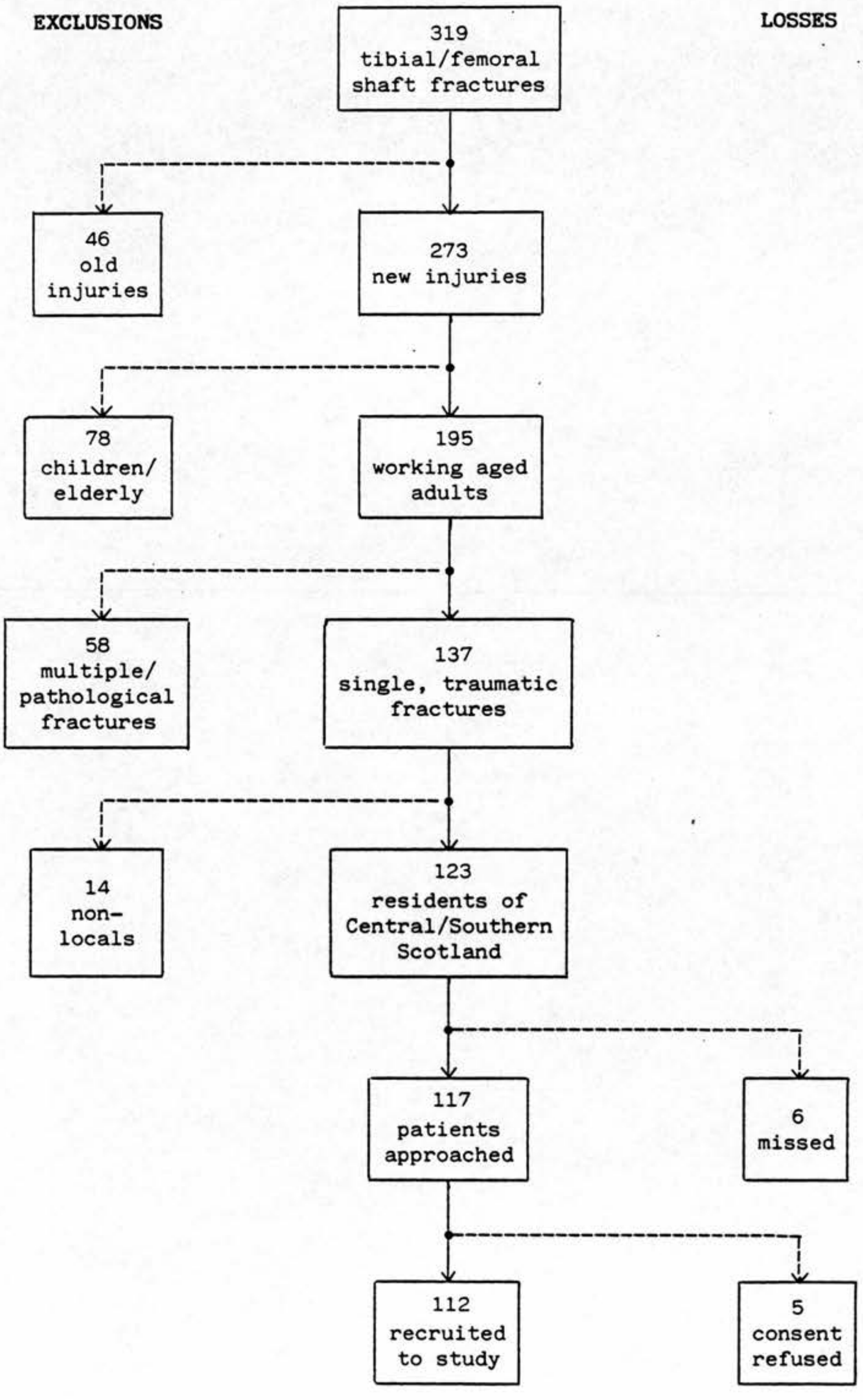
The way in which these criteria were applied is described later in this chapter (see Procedure).

An initial series of 11 patients was used to pilot the recruitment interview and procedures in January, 1985, and this group was followed up 16 weeks and 38 weeks after their fracture to pilot the first and second home interviews. These pilot interviews were conducted throughout May and October, 1985.

There was a little delay in obtaining the unanimous approval of the Trauma Group to continue with a descriptive study. However, permission was granted in mid-June and recruitment to the main series of subjects commenced on 16 June, 1985 and ended on 18 August, 1986.

A total of 319 potentially eligible patients were admitted to the orthopaedic wards at the RIE during this 14 month period of recruitment (see Figure 1). Of this number, almost two thirds were excluded because they did not meet the inclusion criteria set out above. In addition, six people were missed while they were in hospital and, despite attempts to trace them following their discharge, they were lost to the study. A further five people declined to take part. Three of these five people were older women who were disinclined to take part in a study which was not going to benefit them, personally. One young man refused consent without giving a reason and one older man would not take part without payment. Therefore, in all, 112 patients were recruited as subjects and interviewed whilst in hospital. By the first home interview, this number reduced to 105 (94%), while 97 (87%) subjects were successfully interviewed, at home, a second time. These rates of attrition compare very favourably with

Figure 1: Patient Admissions and Subject Recruitment



the results of other longitudinal studies which have reported losses in the order of 30-40% for studies in the USA, although similar studies in the UK have reported relatively small losses (Wall et al, 1970).

The decision to stop recruiting patients to the study was determined by the fact that, due to other commitments, fieldwork for the study had to be completed by mid-May, 1987. With a nine month follow-up programme, this meant that recruitment had to cease in August of the preceding year.

3.3. Study Design

The research reported in this thesis was designed as a longitudinal study (Wall et al, 1970) of patients who sustained a particular type of injury. At the outset, the intention was to monitor consenting subjects, who fulfilled the criteria set out earlier, at periodic intervals from early after their admission to hospital to a maximum of nine months (or to union, had this not occurred within nine months). During this period, comparative data was collected routinely at pre-determined intervals during each subject's recovery and, where possible, in similar environments (see Procedure).

For practical reasons relating to the time-tabling of interviews, each subject was seen on three occasions only. With an anticipated recruitment rate of three to four subjects per week, this meant that at the peak of the fieldwork the researcher would be conducting up to 12 interviews per week - each lasting two hours. As the scheduling of home interviews was to be at the convenience of subjects and was to entail evening or weekend appointments, it was not feasible to commit one interviewer to more than three interviews per person.

These three interviews were designed to take place: during the first week of injury; during the 16th, or exceptionally the 17th, week following injury; and during the 38th, or exceptionally up to the 40th, week following injury. It was planned that the first interview should take place soon after the person was admitted to hospital. This admission interview enabled contact to be made with patients. The study was explained to them. Their signed consent was obtained and base-line information was gathered with respect to their former involvement in social and recreational activities.

The scheduling of the second interview was designed to take place during the 16th week following injury because this was one of the earlier "average" times to union quoted in the literature (see Chapter 2.3). Consequently, it was a time by which some cases of fracture would be declared to be united, while it was anticipated that the majority of subjects would still be experiencing functional difficulties. The timing of this interview was crucial and, therefore, every effort was made to visit subjects in their 16th week post-injury.

The phasing of the third, and final, interview was determined by practical and methodological considerations. Practically, every attempt was made to maximise the number of subjects included in the trial. The longer the follow-up period, the fewer the number of subjects who could be fitted into the time-scale for the fieldwork. However, of equal importance was the need to follow-up patients for as long as possible to ensure that they achieved a number of, if not all, the required outcomes in the allotted time. Since, it was forecast that the inter-rater reliability testing of the bone scanning technique would take approximately 18 months, the overall time-plan for the fieldwork was based upon this estimate. With some 200 eligible patients admitted to the RIE each year (see Chapter 1.3) it was predicted that six months of recruitment, with a follow-up period of 12 months, would produce a maximum of 100 potential subjects.

Alternatively, clinical experience suggested that a nine month interview was likely to elicit useful information about subjects' resumption of work and sporting activities. As it was estimated that nine months of recruitment, with a follow-up period of nine months, would result in a maximum of 150 subjects in the trial, this was judged to be the more desirable target.

Following completion of the last interview for each subject, the Research Associate returned to the person's hospital notes and x-rays in order to extract clinical information about each patient's presenting condition and clinical recovery. It was planned that the clinical data should be collected prospectively by a medically qualified colleague. However, this proved impracticable and so the task was undertaken by the author in addition to her interview commitments. Thus, in order to minimise observer bias, none of the clinical information was gathered until the last follow-up interview for each individual had been completed. This meant that, although less desirable, the clinical data had to be collected retrospectively and, therefore, it was subject to inaccuracies and omissions. Nevertheless, it was felt to be preferable to collect data retrospectively, than to exclude clinical variables altogether.

3.4. Research Instruments

Unlike experimental research where specific hypotheses are tested using specific tests, descriptive research is exploratory. Often, it explores circumstances about which little is known and, therefore, a large amount of information can be collected in order to describe complex, multi-dimensional situations. The descriptive study outlined here posed a slightly different problem in that innumerable articles had been written on the subject of tibial and femoral shaft fracture. In this case, it was not a lack of information, but rather questions about the **accuracy** and **consistency** of existing data which prompted the further need to document recovery following these injuries. In addition, the intention was to extend clinically focussed descriptions to include socio-economic, psychological and functional factors - since recovery following fracture was seen to be as much a matter of restoring a person to their former way of life, as it was concerned with the repair of a broken bone.

Thus, in devising the research instruments discussed in this section, the types of clinical variables which could have been included were apparent, but there were no guidelines available to suggest what other variables might have been appropriate. So, one of the first steps in designing research instruments was to make an extensive list of clinical variables of interest. This list was compiled from the literature and from consultations with clinical colleagues within the Department of Orthopaedic Surgery. Other variables were added as the result of discussions with rehabilitation professionals within the Rehabilitation Studies Unit. A number of variables were derived from rehabilitation literature or from previous research conducted by the Research Associate and, yet others, were included because, intuitively, they were felt to be relevant by the author.

Having compiled a list of several hundred potential variables, the relevance of each one was re-examined in the light of practical constraints governing the overall design of the study. Each subject was to be seen on three occasions; the first of which was to be in hospital, while the latter two were to be conducted in the person's own home. In addition, clinical data were to be collected, retrospectively, from the patient's hospital notes and x-rays. Since it was considered unreasonable to request longer than two hours of a subject's time for each meeting, data obtained by interview had to be restricted and organised in such a way as to result in no more than three, two-hour interviews. Accordingly, variables were organised into four categories of items depending upon when the information was to be collected:-

- admission data
- 16 week follow-up data
- 38 week follow-up data
- clinical data

The computer compatible coding frames for each of these data sets are contained in Appendix II. In the appendices, these forms are white, but fact, each interview schedule was printed on different coloured paper to distinguish each from the others. For reasons explained later in the text, pages two and three of the admission data schedule are reproduced in the clinical data schedule. Only the second of the two home interview schedules has been included in the appendix because the two were identical in all but the last page of the second form. A brief description of the four instruments follows.

3.4.1. Admission data

The coding frame to collect admission data was white and comprised a 10-paged form (see Appendix II.I). With the exception of the second and third pages which itemised clinical admission data and will be discussed later (see Clinical Data), the form was designed to: identify subjects; to collect socio-economic information about their circumstances and to record base-line information about their level of pre-injury activity - particularly in relation to social contacts, the use of transport and previous sports involvement.

Subjects were identified by consecutive numbering according to their order of recruitment to the study. Other details (such as their date of birth, ward, hospital number, Consultant, date, day and time of admission, bone and leg injured) were recorded in order to facilitate the tracing of patient notes and x-rays at a later stage in the fieldwork. This data provided the Research Associate with the minimum detail necessary to approach individual patients.

Variables included in this schedule were organised under five main headings:-

- personal details
- injury details
- home circumstances
- employment
- pre-injury activity

3.4.1.1. Personal details

Items covered under this heading included the subject's age in years at the time of injury; their marital status; their occupation and social class (both of which were coded using the Office of Population Censuses and Surveys' Classification - OPCS, 1970); whether or not their notes mentioned that they had consumed alcohol prior to injury; and their region of residence. All the forementioned items were coded from information recorded in the ward admission books or hospital records.

3.4.1.2. Injury details

Details relating to the place and circumstance of injury were obtained directly from the patient by structured interview. A structured interview was adopted because it was recognised that there were problems associated with obtaining data by interview. For example, Orenstein et al, (1978) cite problems associated with "yeasayers and naysayers", the effect of the interviewers race, status, and sex upon respondents replies, together with the "social desirability" of questions, as potential sources of bias. Thus, in order to minimise these influences, a structured interview was conducted with all subjects so that the interviewer could bias the situation as little as possible.

A distinction was made between injuries that had occurred at home, at work, whilst playing sport, as the result of a road traffic accident (RTA) or elsewhere. In the case of RTA's, further information was sought as to whether the subject had been a pedestrian, a driver or a passenger and what type of vehicle was involved. The circumstances of the injury were recorded in relation to whether injury had resulted from a trip, a fall, a collision with a person or direct personal violence, violence caused by an object, or some other form of injury.

3.4.1.3. Home circumstances

Variables recording the home circumstances of subjects were included to establish whether the person lived with anyone else and, if so, their relationship with and the number of other people in the household. Subjects were asked whether they had dependents, if they had stairs to negotiate at home and if they rented or owned their home.

3.4.1.4. Employment

Subjects were questioned whether, prior to injury, they were in paid employment and, if so, whether they held a full or part-time post. For those subjects who were not previously employed, they were asked whether they considered themselves to be unemployed, retired, a housewife or a full-time student. Subjects formerly working, were asked how many years they had been in their current job and what this job entailed. People living with a partner were asked whether their partner worked and, if so, whether this was part-time or full-time.

3.4.1.5. Pre-injury activity

Finally, information was requested about each subject's former levels of activity. A note was made of their ease of mobility prior to injury and, where applicable, their use of walking aids. Since the majority of fractures were likely to have resulted from RTA's and sports injuries, it was decided to code activity in relation to social contacts, the use of transport as a passenger or driver and previous involvement in sport. Subjects were asked how frequently during the month before their injury they performed specified activities. An ordinal, four-point scale was devised for this purpose which categorised responses into: never, less than once per week, once per week, and more than once per week. This scale was chosen because it gave sufficient sensitivity to distinguish regular participants of a particular activity from irregular or non-participants, whilst also providing categories which were broad enough to minimise errors of coding. It was hoped that this would increase the likelihood that the resultant data would be reliable over time and between raters.

Social items coded using the above scale covered frequency of: shopping; visiting friends and relations; visiting social clubs, pubs or centres; taking part in leisure activities excluding sport; attending appointments (eg GP, hair); involvement in entertainments (eg cinema, theatre); and participation in other social activities specified by the subject. Frequency of using forms of passenger transport included how often subjects had: caught buses or trains; rode as a pillion passenger on mopeds, scooters or motorbikes; or travelled in cars, vans, or other vehicles. Subjects were asked how often they rode a bicycle or drove a moped, scooter, motorbike, car, van or other vehicle. With respect to sport, subjects were asked how frequently they had played rugby, football, skied, played contact sports, racket sports or other ball games during the month prior to their injury or during the preceding season.

The final two questions on the admission data schedule where open-ended questions asking about the subject's hobbies, leisure pursuits and household responsibilities. These questions were included as a means of checking whether the frequency data adequately covered the most common activities performed by subjects.

All the variables noted on the admission data schedule (including the clinical items) were independent variables designed to collect descriptive details about subjects and their presenting injury.

3.4.2. 16 Week follow-up data

The second interview schedule was used to record data collected during the 16th week following injury. This form was printed on pink paper (see Appendix II.II), comprised 13 pages and had six main sections covering:-

- mobilisation
- employment
- rehabilitation services
- post-injury activity

- examination and
- functional movement

Information for this schedule was elicited by observation, questioning and measurement.

3.4.2.1. Mobilisation

The section on mobilisation noted whether the subject's injured leg was externally immobilised at the time of interview and, if so, the type of external device in place. A record was made whether the subject was walking and taking weight through his injured leg. If the person was fully weight-bearing without walking aids, he was asked whether he felt he walked normally, with a slight limp or with a pronounced limp. The subject was then asked about his experience of pain. For subjects who reported that they were experiencing pain at the time of interview, they were asked to complete Questionnaire One (see Appendix II.III) which was a redesigned version of the McGill Pain Questionnaire (Melzack, 1975). In addition, questions were asked about pain experienced when subjects walked, were at rest, or went to bed.

3.4.2.2. Employment

Subjects who were employed at the time of their injury were asked whether they had returned to work and, if not, whether their job was still available. For those subjects who were back at work, they were asked questions about the ease and timing of their return.

3.4.2.3. Rehabilitation services

During the period of recovery to the time of interview, subjects were asked whether they had had any contact with a specified list of rehabilitation professionals, vocational rehabilitation personnel and work personnel.

3.4.2.4. Post-injury activity

General questions were asked about whether or not subjects felt they had resumed all their former social activities, hobbies, sports, and use of transport as a passenger and driver. This information was supported by frequency data summarising their involvement over the preceding month in the same way as described for the admission data schedule.

3.4.2.5. Examination

At this point in the schedule, the format changed from interview to assessment with the requirement to examine, visually and physically, the subject's legs. Throughout the examination, comparisons were made between the injured and uninjured limb. A note was made whether the injured limb appeared deformed in any way, either because of scarring, prominent callus or malalignment. The fracture site was palpated and gentle pressure applied over a similar area on either leg. Subjects were asked whether either site was tender and, if the fracture site was, this was recorded.

Next, subjects were asked to either sit on the floor or sofa (if one was present). Comparative measurements were taken of the girths and lengths of the relevant part of the lower limb according to whether the subject had sustained a tibial or femoral fracture. For subjects with tibial fractures, the girth of the widest part of the calf of their unaffected leg was measured and the level of this measurement below the tibial tuberosity was noted. The examiner moved to the affected leg, measured an equivalent distance down from the tibial tuberosity and recorded the circumference of the calf at this level. The difference between these two circumferences was recorded as being either less than 2cm or 2cm or more. A similar procedure was followed for subjects with a fracture of their femur only measurements were taken at a point where vastus medialis was bulkiest when their leg was straight. The level of this measurement was taken from the proximal edge of the patella.

The presence of neurological weakness in the muscle groups of the lower limb was noted only when gross impairment was evident, as in the case of a peripheral neuropathy. Subjects were asked to demonstrate their ability to bend and straighten their knee and dorsiflex and plantarflex their ankle as proof of an intact motor system.

In the case of the tibia, real shortening of the affected limb was measured from the middle of the lateral aspect of the knee joint to the tip of the lateral malleolus and compared with the equivalent measurement from the unaffected limb. For the femur, the procedure followed was the same, but measures were taken from the greater trochanter to the middle of the lateral aspect of the knee joint. The separate measurements were recorded and the differences were calculated to the nearest centimetre.

Knee and ankle ranges of movement were recorded for all subjects. Originally, the intention was to measure hip and subtalar movement as well, but attempts to measure these ranges were abandoned during the pilot study because, in practise, they were too difficult to perform and reproduce in the different home environments. All measurements were taken using one universal goniometer with long lever arms. Subjects were requested to adopt a half-lying position. For knee measurements, the fulcrum of the goniometer was placed over the middle of the lateral aspect of the knee joint. The proximal arm of the goniometer was aligned with the greater trochanter and the distal arm with the lateral malleolus (Norkin et al, 1985). Three measurements were recorded for each direction of movement, the goniometer being removed and repositioned each time. An average of these measures was used for analysis purposes.

Dorsiflexion and plantarflexion were measured by positioning the fulcrum of the goniometer over the lateral malleolus and aligning the proximal arm with the head of fibula while the distal arm was held parallel with the fifth metatarsal (Norkin el al, 1985). For ankle movements, the subject was positioned in half-crooked lying. The starting position at the ankle was set to 90° before each measurement and for each direction of movement.

Knee and ankle ranges of movement were recorded for both the affected and unaffected limb where both limbs were unimpeded. However, when an external cast prevented measurement of the affected limb, as in the case of a patella tendon bearing (PTB) plaster being *in situ*, neither the affected nor the unaffected joint was measured.

The decision not to measure the unaffected limb under these conditions was taken because it would have been unreasonable to request subjects to take up positions which were awkward to maintain with a PTB or other cast on their leg. Equally, it was not appropriate to modify these standardised starting positions. Therefore, repeat measurements for the knee and ankle joints of the unaffected leg were undertaken only when the corresponding joint on the affected leg was unrestricted.

3.4.2.6. Functional movements

Functional recovery was coded using 21 items derived from the Activity Matching Ability System - AMAS (Sinclair et al, 1984) which related to lower limb functions such as prolonged standing, running, climbing stairs and lifting (see Appendix II.II). Subjects were asked to identify those functional demands which they **needed** to be able to do in order to perform their job or other pastime and household activities. For those items which were identified as essential movements or positions, subjects reported whether, in their own opinion, they were able, had difficulty with, or were still unable to perform each specified activity relative to the demands usually required of them at work or elsewhere. In this way, an attempt was made to record a subject's rehabilitation requirements and abilities in relation to their level of functioning prior to injury. Clearly, if a person was not someone who ever ran before injury, there was little point in striving for this outcome following injury (the aim of treatment being to restore a person to their former state). The development and scientific evaluation of AMAS has been described elsewhere (Watson, 1987). The purpose of including items relating to lower limb function in this study was to assess the ability of subjects to report accurately the physical demands they faced at work and elsewhere, in order to assess the potential for using part of the AMAS scheme as a basis for evaluating functional outcome following lower limb fracture.

As a final, more general, adjunct to the functional data, subjects were asked how satisfied they were with their recovery. Their responses were recorded on a seven-point, ordinal scale ranging from extremely dissatisfied to extremely satisfied and the reasons for their satisfaction or dissatisfaction were noted, along with any other comments which they made.

3.4.3. 38 Week follow-up data

The third, and final, interview schedule, designed to collect data from subjects in their 38th week following injury, was set out in an identical format to the 16 week interview schedule with the exception that an additional page was attached. This schedule was printed upon blue paper and comprised 14 pages, with the same sections and variables outlined for the 16 week interview.

The repeat data collected at this point in time fulfilled two purposes. Firstly, information relating to the subjects recovery was up-dated. So, for example, a subject who was partially-weight bearing 16 weeks after their injury often was fully-weight bearing at 38 weeks. Secondly, were the situation was unchanged, collecting data a second time provided the opportunity to check the intra-rater reliability of the data (since one Research Associate conducted all the interviews). For example, measurements taken from the unaffected limb on two occasions could be compared - the ideal being that the results would demonstrate a perfect, positive correlation. Similarly, for subjects who had neither changed their jobs nor pastimes, their reported need to perform various functional activities could be compared at 16 weeks and 38 weeks for each variable.

The additional items included on the last page of the schedule were set out under the headings:-

- insurance
- household finances and
- return to work

3.4.3.1. Insurance

Subjects were asked whether they, themselves, paid the premiums for a personal insurance policy and, if so, whether this was for personal accident, permanent health or both.

In other cases where a personal injury claim was being made for third party liability or criminal injury, subjects were asked whether this was an employers' liability claim, a motor claim, a public liability claim or another type of claim which they were asked to specify. They were also asked about the progress of their claim.

3.4.3.2. Household finances

Subjects were asked about their financial circumstances during their period of incapacity following fracture and whether this had resulted in their income being reduced, maintained or increased during this time.

3.4.3.3. Return to work

As a footnote to the last page of this schedule, return to work data was converted into the number of weeks following injury where this was possible and appropriate. The calculation was based upon information provided by subjects at their 16 week or 38 week interview. If subjects had returned to work by either of these times they were asked the exact date of their return. Since their date of admission to hospital was known and, usually, this was the date of injury too, it was possible to calculate the week they returned to work. (A separate note was made of the date of injury for those people who were transferred to the RIE from another hospital and, hence, their date of admission and date of injury were not the same.)

3.4.3.4. Psychological data

Three questionnaires were used, in conjunction with the interview coding schedules in order to collect psychological data. The first questionnaire, Questionnaire One (see Appendix II.III), was concerned with pain and was completed only if subjects reported that they were experiencing pain at the time of their 16 week or 38 week interview. As stated earlier, this questionnaire comprised a re-typed version of the McGill Pain Questionnaire described by Melzack (1975).

The second questionnaire, Questionnaire Two (see Appendix II.IV), was based upon the Health Locus of Control (Wallston et al, 1978) and was designed for self completion. In the presence of the Research Associate, subjects were asked to respond to each of 11 statements about health (on a six-point, Likert-type, ordinal scale ranging from strongly disagree to strongly agree) by ringing the appropriate number corresponding to the response which was nearest to their own opinion. The questions were divided into five internally worded items and six externally worded items, the scorings for which were reversed to create two, separate sub-scales known as the I-E scales. In turn, these sub-scales were summated into a total HLC scale. The test was chosen for inclusion in the study because it was hypothesized that higher internal control might be associated with a more favourable outcome. Furthermore, the tests had been validated for predicting health-related behaviour and the intra-rater reliability for the HLC scale had been established as 0.71 (Wallston et al,1976), so exceeding the criterion of 0.70 set for this study (see Objectives).

Questionnaire Two was completed by all subjects at the end of their 16 week and 38 week interview and was handed back to the Research Associate before she left each subject's home.

The third questionnaire, Questionnaire Three (see Appendix II.V), was based upon the Work and Life Attitude Scales described by Warr et al (1979) and comprised some 68 items arranged into 11 sub-scales, many of which sought seven-point responses, although five-point and three-point scales were used for a minority of items. Like Questionnaire Two, tests of validity and reliability had been performed using these scales and, despite the fact that the correlation coefficients quoted for these sub-scales fell below (Warr et al, 1979) the 0.70 criterion established for this study, the questionnaire was used because the authors claimed that their results were "acceptably high relative to measures in the literature and to the internal homogeneity of the scales". Once again, the questionnaire was designed for self-completion, but it was given only to subjects who were employed at the time of injury. Because of the length of this questionnaire, subjects were asked to complete it at their leisure and post it back to the Research Associate in the stamped, self-addressed envelope provided. This questionnaire was intended to be completed at 16 weeks and 38 weeks by all previously employed subjects.

3.4.3.5. Rehabilitative dependent variables

Although many of the variables included in both follow-up schedules were intended to be evaluated as potential measures of outcome, the most important of these were:

- range of joint movement
- return to work
- resumption of activities (ie social contact, hobbies, sport, use of transport, household duties)
- ability to perform necessary functional movements

3.4.4. Clinical data

As already stated, it was intended that a medically qualified colleague would collect the clinical admission data soon after patients arrived in hospital and the clinical follow-up data once the last home interview had taken place. For this reason, the coding frame for the clinical admission data had been included in the admission data schedule because these data were to be coded and entered on computer together. However, as the Research Associate collected all the clinical data, retrospectively, these pages were extracted. Therefore, the clinical data schedule comprised five pages - two of which were white and were used to code admission data, while the remaining three were green and were used to code the clinical follow-up data (see Appendix II.VI). Variables included in this schedule were arranged under six major headings:

- initial fracture classification
- other injuries
- known medical history
- treatment summary
- complications
- clinical result

3.4.4.1. Initial fracture classification

The classification of diaphyseal fractures had been approached in a variety of ways already (see Chapter 1.3), few of which were satisfactory in terms of the definitions provided or the scaling used. Therefore, it was decided to treat each variable separately rather than attempt to combine them into a multivariate scale. The variables included under this heading were; severity (ie simple or compound fracture and grade - Gustilo et al, 1976); site (ie upper 33% of diaphysis, middle 34-66%, or lower 67-100%); initial displacement (ie none, less than 50%, 50% or more); angulation (ie varus or valgus in degrees); pattern of fracture (ie transverse - defined as less than 20°,oblique - defined as 20° or more, spiral, double, or comminuted - defined as having one or more fragments); degree of comminution (Winquist et al, 1984); associated fibular fracture (ie no/yes and, if yes, level); and associated injuries (ie skin deficit, neurological deficit, tendonous injury, ligamentous injury, vascular injury or other injury).

Information about the severity of injury and the presence of associated injuries was obtained from patient notes. The remaining data were extracted from the initial casualty x-rays following the procedures outlined below..

The site of injury was established by measuring the length of the diaphysis and dividing this into upper, middle and lower thirds. However, in practise, x-rays rarely included both the upper and lower ends of the bone and, even when they did, a judgement had to be made as to where the diaphysis met the metaphysis. Inevitably, there was some question as to the reliability of this data.

The initial displacement demonstrated between the fragments was established from the antero-posterior (AP) and lateral casualty x-rays taken at the time of admission. The diameter of the diaphysis across the mid-point of the fracture was measured on both views and was coded according to the greatest discrepancy between fragments. So, for example, when there was no displacement detectable on the AP view, but less than 50% displacement on the lateral view, this latter finding was recorded.

Angulation was measured from the AP view of the casualty x-rays. A line was drawn along the longitudinal axis of each fragment by measuring the diameter of the diaphysis just above and below the fracture site and again nearer each bone end. The two points on each fragment were pencilled onto the x-ray and each line was subtended until they crossed. The acute angle formed by these two lines was measured and recorded, irrespective of whether the misalignment was varus or valgus.

Similarly, the pattern of fracture was ascertained from the AP view of the casualty x-rays. Where the fracture appeared as a clean line, a distinction was made between a transverse and oblique pattern by measuring the angle the fracture line made with a line running vertically across the diaphysis of the distal fragment. If this angle was less than 20° it was recorded as a transverse fracture. Whereas, if it was 20° or more, it was recorded as an oblique fracture. Spiral, double or comminuted fractures were distinguished by their appearance on x-ray, but were confirmed from the orthopaedic summaries in patient notes.

Comminuted fractures were graded according to Winquist et al's (1984) classification by counting the number of fragments which were visible or by measuring the relative extent of the intact part of the most damaged fragment.

For subjects who had sustained a tibial fracture, note was made of the presence or absence of an associated fibular fracture and, if present, whether this was at the same or a different level. The presence of a fibular fracture was evident from the casualty x-rays and, again, confirmed from the orthopaedic summary in each subject's notes. The level of fibular fracture was established in relation to the site of the tibial fracture by dividing the diaphysis into thirds as described earlier.

3.4.4.2. Other injuries

Apart from those soft tissue injuries associated with the fracture site, itself, a record was kept of the other, secondary injuries sustained at the time of fracture. By design, any other injuries were of a lesser severity than the tibial or femoral fracture because this was specified as one of the criteria for entering subjects into the study.

3.4.4.3. Known medical history

Existing medical conditions which might have affected recovery were coded according to whether these were: cardiac, respiratory, locomotor, neurological, endocrine, sensory, psychological or other conditions.

3.4.4.4. Treatment summary

The first three treatments undergone by subjects were coded according to the method of reduction and stabilisation used. A distinction was made between subjects initially treated by: cast only, manipulation and cast, external fixation, internal fixation and other methods such as traction. Subsequent methods of treatment included the remanipulation of fractures which had lost position, secondary external fixation, secondary internal fixation and bone grafting. Note was taken of the number of days or weeks after injury that these treatments were undertaken. For example, a fracture which had been stabilised in a cast, remanipulated due to a loss of position and internally fixed some weeks later would have been recorded as having undergone three treatments. The application of the initial cast would have been noted in days following injury, while the timing of the other two procedures would have been recorded in weeks.

If a cast had been applied at any stage of treatment, a note was made of the number of weeks after injury that it was removed. Similarly, the week following injury that subjects were instructed to non-weight bear, partially-weight bear and fully-weight bear was recorded if this was documented in their hospital notes.

3.4.4.5. Complications

The hospital notes were scrutinised for evidence to suggest that subjects had experienced any of the following complications: compartment syndrome, ischaemic contracture, skin problems, clinical infection, shift or angulation of the fragments, "delayed" or "non-union" or any other specified complication. Because this review was retrospective, there was no guarantee that complications had not arisen simply because they were not mentioned in the hospital notes. Occasionally, the absence of a particular complication was recorded by clinicians in the notes (eg infection).

3.4.4.6. Clinical result

A record was made of those fractures which were said to have "united" by the time the hospital notes were reviewed and the week following injury that this was confirmed. (It was recognised that this data would coincide with the time-tabling of clinic appointments rather than the progress of fracture healing. Nevertheless, the intention was to test the reliability of data collected retrospectively, since this had been the usual method of reporting time to union - see Chapter 2.3.)

Radiological shortening of the bone was recorded in centimetres by measuring the overlap of the fragments at the fracture site on the most current AP x-ray. Alignment was measured in degrees from the same x-ray following the procedure described to measure the initial angulation of the fracture on the subjects admission to hospital. This time, a distinction was made between valgus and varus deformities. It was intended that rotational deformity would be recorded too, but this was impossible since rotation could not be measured from x-rays and the hospital notes rarely mentioned this deformity.

Malunion was noted if union had been confirmed, but the fragments appeared to be angled, displaced or misaligned in any way on the most current x-ray. It was acknowledged that this would produce subjective information, of questionable value, but again the intention was to test the quality of data collected by this means. The presence of venostasis or oedema was coded only if it was mentioned as a persistent problem at the last clinic attendance. Finally, any general comments of interest about either the x-rays or notes were recorded at the end of the clinical data schedule.

3.4.4.7. Clinical dependent variables

The plan was to examine the potential of the following clinical variables as measures of outcome:

- time to union
- the reported incidence of complications (eg clinical infection, late shift or angulation, "delayed" or "non-union")
- the incidence of malunion (eg shortening, valgus or varus angulation)

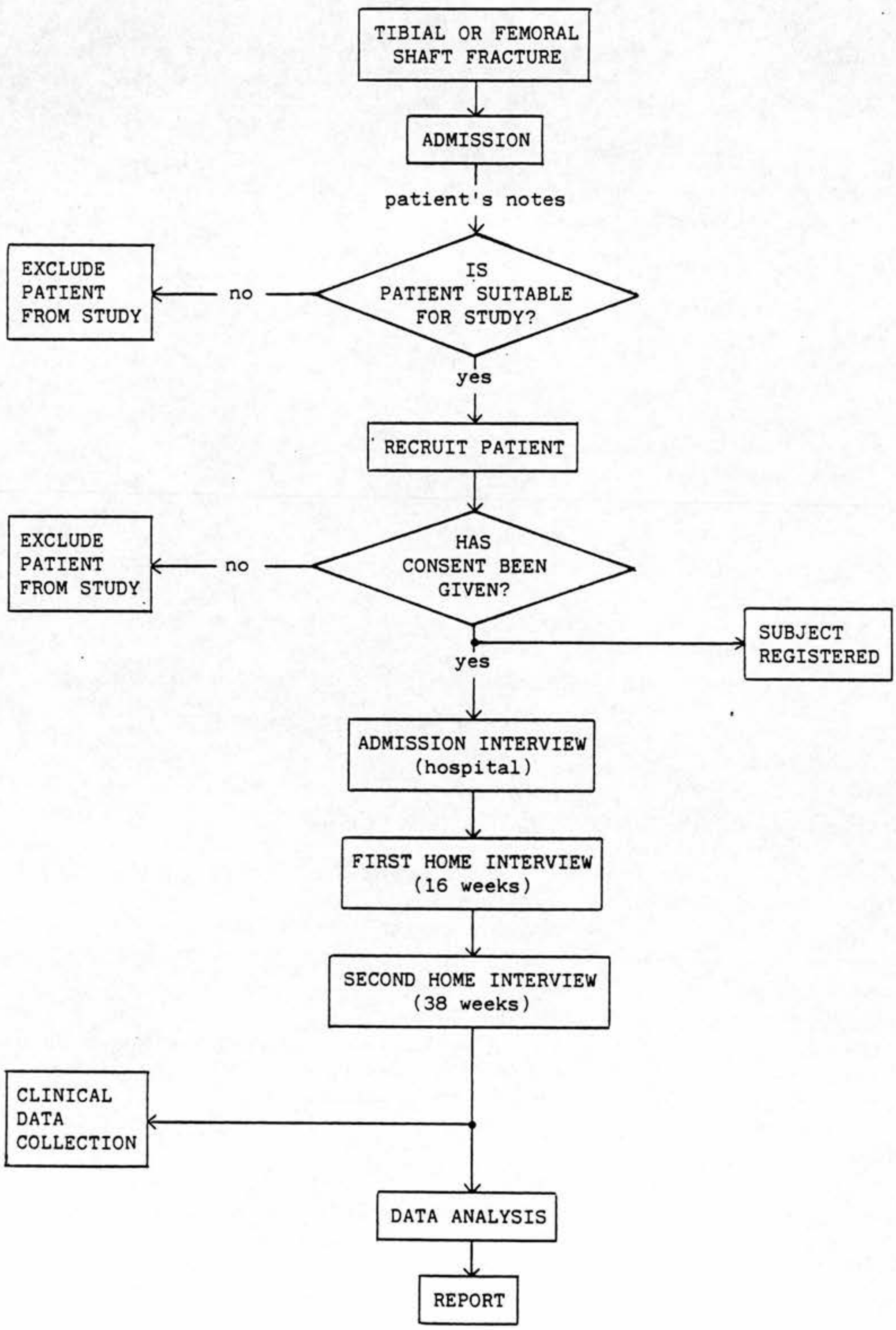
3.5. Procedure

Each subject was monitored from early after admission to hospital to a maximum of 40 weeks following injury - or to union if this had not been confirmed by the final follow-up interview. Data was then extracted, retrospectively, from the hospital notes and x-rays of each subject.

It may be seen from the accompanying figure (Figure 2) summarising the procedure, that each subject was seen on three occasions:

- on admission to hospital
- at home 16 weeks after injury (or exceptionally in the 17th week)
- at home 38 weeks after injury (or exceptionally in the 39/40th week).

Figure 2: Diagrammatic Summary of Procedure



3.5.1. Recruitment and admission interview

Subject recruitment was undertaken by the Research Associate from the total population of patients with tibial or femoral shaft fractures admitted to the orthopaedic wards at the RIE. Every week-day morning for approximately 14 months, the Research Associate visited the orthopaedic wards in the RIE to check the ward admission books. A list of patients suitable in terms of age and fracture type was compiled from the admission book for each of the three wards (see Subjects). Then, the casualty notes and orthopaedic summary for each patient was consulted to establish the cause of injury and that the person lived in Central or Southern Scotland and, hence, was eligible for entry into the study.

Eligible patients were approached, personally, and the purpose of the study was explained to them. Each patient was given a written summary (see Appendix II.VII) of the study, together with the name, address and telephone number of the Research Associate to whom they could address enquiries regarding research arrangements following their discharge from hospital. The verbal agreement of patients to take part was accompanied by their signed consent to participate in the study (see Appendix II.VIII).

Once consent had been granted, subjects were allocated a number and their details were recorded in a subject register. Consecutive numbering was employed to identify patients and this number was used from then onwards to identify data kept in both the manual and computerised files.

Following the recruitment of a subject, two identical cardex entries were made recording the name, address and subject number of each patient. One of the cards was filed alphabetically in case subjects rang in to enquire about interview times or provide information about a change of address. The second card was filed numerically according to subject number and was the working file - cards being taken out for the purpose of contacting subjects to arrange their follow-up interviews. In addition, two appointment diaries were kept to record the week subjects' interviews were due and the actual appointment times and dates.

Once a patient was registered as a subject, they were interviewed whilst still in hospital. This interview took approximately one and a half hours to complete.

3.5.2. First home interview

Subjects were contacted by telephone or letter (see Appendix II.IX) in their 15th week after injury so that an appointment could be arranged to see them, in their own home, the following week. Appointments were made at a time convenient to the individual concerned during the day time, evening or week-end.

If a subject could not be contacted during their 15th week, attempts were made to do so throughout their 16th and 17th week. However, subjects who had not been seen by the end of their 17th week were lost to this interview.

In general, subjects were very conscientious about informing the Research Associate of their whereabouts and keeping appointments. Nonetheless, a certain amount of ingenuity and perseverance was required in order to trace and arrange to meet a number of individuals. Two of the more unusual venues where interviews were conducted were Glencorse Barracks and the Royal British Hotel. One subject broke four evening appointments before she was interviewed successfully. Another subject had to be interviewed by telephone because he was working in the Midlands at the time.

Each structured interview took approximately two hours to complete and followed a prescribed format (see Research Instruments). During the same attendance, the Research Associate administered three psychological questionnaires as indicated. Questionnaire One and Two were completed at the time of interview, while Questionnaire Three was left with subjects (who had been employed prior to injury) and returned by post.

3.5.3. Second home interview

A second home interview was arranged for all subjects during their 38th week after injury. This interview was a repeat of the 16 week interview with the addition of questions relating to insurance cover and the home finances of subjects during the preceding 38 weeks.

Where possible, subjects lost to the earlier interview were included in the programme of fieldwork at this stage. However, in practice, subjects lost to the initial home interview generally were lost to the subsequent one as well.

To conclude this last interview, subjects were thanked for their participation and asked whether they would like to receive a brief summary of the findings of the study when available. Anyone wishing to read the final report was invited to contact the Rehabilitation Studies Unit once they had received the summary paper so that arrangements could be made for them to borrow a copy of the full report.

3.5.4. Clinical data collection

Each subjects' notes and x-rays were reviewed once their last interview had been completed. In order to accomplish this task, each set of notes and x-rays had to be traced within the various filing systems at the RIE and outlying hospitals. Next, the necessary arrangements had to be made to borrow each set of documents and, finally, they had to be replaced from whence they were borrowed. This exercise was extremely time consuming, frequently involving the checking and rechecking of several sources before sets of documents were found. In certain instances, patients were followed-up at clinics outside the Lothian Health Board area and, so, their notes and x-rays were not available for review. In other instances, the original notes or x-rays were known to be missing.

Data were extracted, systematically, from each set of notes and x-rays using the clinical data schedule and procedures described earlier in this chapter (see Clinical data). The review took from one to two hours depending upon the complexity of each persons' history.

The Research Associate was responsible for returning the records into the hospital filing system once the necessary data had been extracted. Nevertheless, on more than one occasion documents had to be returned prematurely because they were needed for a clinic. While it was essential that the research requirement for notes and x-rays did not interfere with routine, hospital procedures, the fact that most people were still being followed-up at clinic meant that the task of reviewing the clinical data was all the more difficult.

3.6. Summary

This chapter has described the methodology and procedures adopted for a longitudinal study of a specific population of orthopaedic patients recovering following a fracture of their tibial or femoral shaft. The study aimed to select and test instruments capable of measuring physiological, socio-economic, psychological and functional outcome, whilst also aiming to describe the patient population and investigate the potential effect of independent variables upon outcome (eg site of fracture, infection and social class). To achieve these aims, standardised research instruments were designed to enable data to be collected in a systematic manner, at particular points in time during recovery and following precise instructions. It was intended that the reliability of all variables should be examined, but that the properties of measurement for potential dependent variables should be evaluated in greater detail.

The next three chapters present the results of this endeavour. Chapter 4 deals with the verification and testing of data and the evaluation of a limited number of dependent variables as potential measures of outcome. In the light of the accuracy of these data, Chapter 5 describes the patient population in terms of their personal characteristics, their presenting injuries, the treatment they received and their subsequent recovery. Finally, Chapter 6 examines the potential effect of various characteristics of patients and "personality" of fractures upon outcome using time to union, return to work, health attitudes (measured using the total HLC scale) and the ability to kneel as the dependent variables for this exercise. This chapter also presents the results of two stepwise regression analyses using survival functions to examine the relative importance of select independent variables upon time-to-response data relating to union and return to work. In this context, four null hypotheses have been tested to exemplify the use of the technique for hypothesis testing.

CHAPTER 4

VERIFICATION AND TESTING OF THE DATA

4.1. Introduction

This chapter describes the process by which data, collected during the course of this study, was checked for accuracy and consistency. It also describes the means by which potential measures of outcome were tested and presents the results of these exercises.

The importance of establishing the reliability of measurement instruments has been emphasised in Chapter 2, but is of no less concern when reporting descriptive data. However, prior to testing this property for all variables it was essential to eliminate errors of coding, transcription and keying data into the computerised database. To this end, every schedule was double checked for errors of coding or copying codes into the data entry boxes on the coding forms (see Appendix II). Next, the computer printout of the data file was checked against each coding form for every subject. Input errors were identified and corrected on the master data file. Finally, cross examinations were made for pairs of items using frequency tables to highlight discrepancies of coding between variables which sought comparable information. This process of verification was time consuming, but essential in order to minimise the confounding affect of errors of coding upon the overall accuracy and consistency of data.

The consistency of data was tested between two raters for the majority of variables and over time for a minority of variables. A considerable commitment was required of fieldworkers in order to conduct interviews according to time plan and to extract clinical data from patients' notes and x-rays. Therefore, it was not feasible to assess the reliability of data on a large number of cases. Furthermore, the recruitment of subjects was unpredictable since patients were emergency admissions and the fieldworkers had to be prepared to conduct interviews at short notice and to undertake at least the first home interview 16 weeks later. For this reason, it was not practicable to ask research staff to undertake this exercise on an informal basis. So, towards the completion of the descriptive study, a second Research Associate/physiotherapist was recruited, to work alongside the author for a period of six months, in order to undergo training and to repeat the data collection for a number of the admission, first home interview and clinical data schedules.

A series of nine patients agreed to be seen by each fieldworker, separately, for their first two interviews. Although, it had been hoped that a minimum of 10 patients would be included in this phase of the work, a total of nine patients were admitted to the hospital during the month of recruitment for this task and seven of these subjects were seen 16 weeks later by both Research Associates. Despite the fact that it would have been preferable to include as many subjects as possible in this exercise, it should be noted that the small numbers made it harder to achieve consistent results and this should be borne in mind when considering the tables later in the chapter.

A separate series of 12 patients agreed to be interviewed twice by the author, while they were still in hospital, so that the intra-rater reliability of the activity data could be assessed. However, whilst subjects were prepared to see two different people for the home interviews, they were less prepared to see the same person twice. Hence, the intra-rater reliability for select variables has been based upon data collected at the 16 week and 38 week interviews. For example, measurements taken from the unaffected leg were assumed to have remained stable over the intervening five months between interviews. Therefore, discrepancies were attributed to measurement error rather than to real changes in the limb. Of course, this assumption may not have been correct. Indeed, the mobility of unaffected limbs may have changed over time, in which case the results reported here will reflect a greater inconsistency of measurement than existed. In other words, the intra-rater reliability measures taken at 16 and 38 weeks may underestimate the consistency of the data.

In addition to confirming the accuracy of interview data, both fieldworkers repeated the collection of clinical data from a random sample of 15 sets of hospital notes and x-rays selected from the main series of cases in order to verify the consistency of clinical information. Once the author had gathered all the clinical data a first time, a random sample of 15 cases was re-examined, quite independently, by both fieldworkers enabling its intra-rater and inter-rater reliability to be assessed.

It was appropriate to test the consistency of data derived for all variables, but a number of these were assessed as potential outcome measures. These dependent variables were evaluated in terms of their sensitivity and content validity, as well as their reliability. Seven dependent variables were singled out for closer examination and these will be discussed in the second part of the chapter. The first section discusses the consistency of data collected for the independent variables which were to be used for descriptive purposes.

4.2. Consistency of Data Relating to Independent Variables

Reliability has been defined already (see Chapter 2) as the degree to which two separate, independent measurements of the same thing agree with one another. For ordinal, interval or ratio data, this is usually expressed as a co-efficient of correlation representing the relationship between two sets of measurements. However, nominal data which categorises information into more than two groups cannot be dealt with in this manner and must be expressed in terms of the number of points of agreement reached between two ratings of the same thing.

To simplify presentation, and for ease of comparison, consistency has been reported as "percentage agreement" and/or as a co-efficient of correlation for all but a handful of variables where this would have been extremely misleading. (For example, where no useful data was recorded by either or both raters.) However, it is recognised that under other circumstances, the small number of cases would not warrant the conversion of results into percentages and so the reader is advised to note the number of points of comparison for each variable and to convert back to actual figures where necessary.

Furthermore, it should be stated that it was not appropriate to calculate statistical significance for the co-efficients of correlation in the present context because the relationship between the two results existed by design and not by chance. Therefore, it was necessary to set an absolute criterion as a cut-off point between "acceptable" and "unacceptable" results. This was set at 70% agreement or a co-efficient of correlation of 0.70 (as indicated in Note (7) these criteria were not equivalent). With certain exceptions, results **falling below** these values were considered to be insufficiently consistent to merit further attention. Future references to "reliability", "stability" or "consistency" are based upon this operational definition.

The results of this analysis are considered under the broad headings of: admission data, follow-up data and clinical data.

4.2.1. Admission data

Six of the variables used to identify subjects were coded for descriptive purposes and, as shown in Table 7, only two of these demonstrated differences in coding between raters. The sex of subjects, their hour and month of admission and the bone involved were coded identically for all 15 pairs of responses. However, while one fieldworker coded the day of admission and the side of injured leg in the same way twice, the second fieldworker differed in her coding of one case for each of these variables. As surprising as this may seem, particularly with respect to coding that a different leg had been implicated, this situation arose from discrepancies documented in the hospital notes. The casualty notes for the subject in question recorded misleading information which was corrected later in the main section of the notes. Only one rater noticed this fact. Nevertheless, the intra-rater and inter-rater agreement obtained for all these variables far exceeded the criterion of 70% required by this study.

Table 7: Intra-rater and Inter-rater Agreement for Subject Identification Variables (N=15)

Variable label	Intra-rater agreement % (r)	Inter-rater agreement % (r)
Sex	100	100
Month	100 (1.00)	100 (1.00)
Hour*	100 (1.00)	100 (1.00)
Day	100	93
Leg	100	93
Bone	100	100

* N=13
(r) Pearsons "r" calculated for ratio data only

The consistency of reporting data for the remaining independent variables included in the admission schedule was tested between the two fieldworkers on data collected from nine subjects. These data are summarised in the next four tables (see Tables 8-11). Table 8 gives the percentage agreement achieved between raters for subjects' personal details such as their age, marital status, occupation, social class, whether alcohol was noted as having been consumed prior to injury and their area of residence. Total agreement between raters was achieved for the marital status variable. Occupation, using the OPCS (1970) classification, was coded differently for two of the nine subjects giving a percentage agreement of 78%. For the other three variables, one subject was coded differently between raters resulting in a percentage agreement of 89%. In the case of age, the Pearson's correlation co-efficient was calculated as r = 0.99 indicating that a near perfect, positive correlation existed between the two recordings. This result suggested that the discrepancy between the actual ages recorded for this one subject was numerically small. Despite the contradictory results noted above, all six variables included under this heading were considered sufficiently consistent to have produced reliable data according to the criterion specified earlier.

Table 8: Inter-rater Agreement for Personal Details (N=9)

Variable label	Agreement % (r)
Age	89 (0.99)
Marital status	100
Occupation	78
Social class	89
Alcohol consumption	89
Area of residence	89

Similarly, the consistency achieved for the five variables describing details of injury were considered adequate between the two raters (see Table 9). Perfect agreement was achieved for the age and place of injury while one point of disagreement occurred for each of the remaining three items. Nevertheless, all the variables exceeded the 70% criterion required here in order to consider data reliable.

Table 9: Inter-rater Agreement for Injury Details (N=9)

Variable label	Agreement %
New injury	100
Place of injury	100
Circumstance of RTA	89
Driver/passenger	89
Circumstance of injury	89

This was not the case for three of the eight variables considered in relation to subjects' home circumstances. As can be seen from Table 10, perfect agreement was achieved between the two raters for coding information about the type and number of people in subjects' households, the type of accommodation in which subjects lived and whether or not a lift was present. Agreement was reached on eight of the nine (89%) codings for the variable relating to home ownership. However, adequate consistency between raters was not achieved for the three variables relating to dependents. Whether subjects had dependents or not, and the type and number of these, was recorded with varying degrees of inconsistency. Only two out of nine cases (22% agreement) were recorded identically for the type of dependents reported by subjects, while 67% agreement was achieved for the other two items. Accordingly, these variables were shown to produce unreliable information and have been excluded from further consideration.

Table 10: Inter-rater Agreement for Home Circumstance Variables (N=9)

Variable label	Agreement %	(r)
Household occupancy	100	
No. of people in household	100	(1.00)
Dependents	67	
Type of dependents	22	
No of dependents	67	(0.93)
Type of accommodation	100	
Presence of lift	100	
Home ownership	89	

Finally, the inter-rater agreement achieved for items relating to employment were all above the 70% criterion of consistency. In one instance, one fieldworker coded a subject as employed while the other recorded him unemployed and, in two instances, the exact number of years of employment did not coincide. However, in this latter case, while there was 78% agreement between the two raters for the exact number of years that subjects had been in their current job, the corresponding Pearson's correlation co-efficient for the data was r = 0.99 demonstrating a near perfect, positive relationship between the two sets of ratio data.

Table 11: Inter-rater Agreement for Employment Variables (N=9)

Variable label	Agreement %	(r)
Employment	89	
No. years in job	78	(0.99)
Partner's employment	100	
Part/full-time	100	

Variables concerned with measuring subjects' frequency of participation in specified social activities, sports and their use of transport prior to injury are discussed in a later section (see Activity measures).

4.2.2. Follow-up data

The consistency of the follow-up data between fieldworkers was checked in relation to data gathered during the first home interview. Ideally, it would have been desirable to collect repeat data for both interviews. However, this was not a practical proposition since it would have meant the two fieldworkers replicating each others work for a period in excess of 10 months. Thus, the follow-up data reported here relates to seven of the nine subjects who agreed to see both fieldworkers 16 weeks following their injury.

One of the original nine subjects was lost to follow-up. The other subject did not have time to see both interviewers during his 16th week post-injury and, therefore, these data have been excluded from the analysis.

Despite the small number of cases reported here, a high level of agreement was achieved between raters for all but one of the variables relating to the mobilisation of patients following fracture (see Table 12). As might be expected, raters totally agreed about whether, and how, the fractured limbs were immobilised and the type of weight bearing demonstrated by subjects. However, when it came to reporting subjects' opinions about the pattern of their gait, only two of the six pairs of responses agreed (33% agreement) confirming that this method of obtaining data was unreliable.

The remaining four variables included in this table were concerned with subjects' reported experience of pain at the time of interview (86% agreement), when walking (71% agreement), when at rest (100% agreement) and whether pain affected their sleep (86% agreement). All of these variables exceeded the required level of consistency specified earlier.

Table 12: Inter-rater Agreement for Mobilisation Variables (N=7)

Variable label	Agreement %
Immobilisation of limb	100
Type of cast	100
Type of weight bearing	100
Gait*	33
Present pain	86
Pain on walking	71
Pain at rest	100
Pain affecting sleep	86

* N=6

The inter-rater agreement for return to work variables reached an adequate level of consistency for all of the items included under this heading (see Table 13). One unemployed subject was coded by one fieldworker as "economically inactive" at the time of follow-up which accounted for the 86% agreement quoted for occupational outcome in Table 13. The other fieldworker mistakenly coded the same subject as being in full-time work with the same employer when, according to alternative sources, he was unemployed. Another subject was coded, by one fieldworker, as having had his job modified on his return because he had been exempt certain duties on his first night back at work. The other fieldworker recorded that he had not had his job modified.

Nonetheless, despite these differences, the remaining four variables were coded identically and, in fact, all produced relatively reliable data (> 70% agreement).

Table 13: Inter-rater Agreement for Return to Work Variables (N=7)

Variable label	Agreement %
Occupational outcome	86
Job availability	100
Return full-time	86
Return to same employer	86
Job modification	86
Job change	100
Persistent problems	100
Timing of return	100

The level of agreement obtained for variables recording the contact subjects said they had had with rehabilitation and work personnel is shown in Table 14. Uniform responses were elicited from subjects reporting contact with a physiotherapist. However, one or two points of disagreement occurred for reported contact with each of the remaining four variables shown in the table. Reported contact with GPs and co-workers provided slightly more consistent data than reported contact with personnel and line managers. There was total agreement between raters for the remaining variables under this heading which have been omitted from the table because no one reported having contact with the other rehabilitation, vocational and work personnel listed under this section (see Appendix II.II).

Table 14: Inter-rater Agreement for Rehabilitation and Work Personnel (N=7)

Variable label	Agreement %
Physiotherapy	100
Contact with GP	86
Personnel management	71
Line management	71
Co-workers	86

Data relating to subjects' resumption of activities was collected in one of two ways. Frequency of participation in specified activities is discussed later in this chapter (see Activity measures). However, subjects also were asked whether or not they considered that they had resumed all their former social activities, hobbies, sports, use of transport and household chores. The percentage agreement obtained for these general questions is displayed in Table 15. The percentage agreement obtained between raters for subjects' resumption of social activity and hobbies was not sufficiently consistent to meet the 70% criterion required of variables. However, comparable levels of agreement for sport, the use of transport (as a passenger and as a driver) and for the resumption of household chores were consistent. Accordingly, the former two variables have been excluded from later analyses.

Table 15: Inter-rater Agreement for Overall Resumption of Activity (N=7)

Variable label	Agreement %
Social activity	57
Hobbies	29
Sport	100
Passenger transport	86
Driving	86
Household chores	86

Part way through the follow-up interview, fieldworkers conducted a physical examination of each subjects' lower limbs. The inter-rater agreement achieved for six subjects for a number of these variables is reported in Table 16. (One subject could not be examined because his leg was still in plaster at the time of interview.) Not surprisingly, determining whether or not limbs were visually deformed prompted contradictory responses from the raters for two out of the six subjects giving an overall agreement of 66%. This was not sufficiently consistent to produce useful data in the context of this study. However, the data coded with respect to subjects' reported tenderness at the fracture site (83% agreement) and the measurement of muscle wasting (100% agreement) and limb shortening (80% agreement) were found to be acceptably uniform. In the latter case, Pearson's correlation co-efficient produced an $r = 0.61$, indicating that the ratio data for the actual measures were not sufficiently reliable to meet the pre-determined criterion of 0.70. In part, this was due to the small numbers involved. Nevertheless, this variable has been excluded from further analyses.

Table 16: Inter-rater Agreement for Examination Variables (N=6)

Variable label	Agreement % (r)
Visual deformity	66
Tenderness	83
Muscle wasting	100
Real shortening*	80 (0.61)

* N=5

The consistency of responses obtained for the three psychological questionnaires (see Appendices II.III - II.V) was evaluated over time and not between raters because these questionnaires were designed for self-completion.

Seven subjects reported experiencing pain at the time of their 16 week interview, while the equivalent figure at 38 weeks was 5 subjects, none of whom had reported pain earlier. Hence, Questionnaire One was not completed twice by anyone. Because of this, no attempt was made to analyse these data.

The intra-rater agreement for Questionnaire Two, the Health Locus of Control (Wallston et al, 1976) was evaluated on 96 subjects over a five month interval. As can be seen from Table 17, the scores for internality, externality and the total scores for individuals were not sufficiently stable between the two applications of the test to meet the 0.70 criterion of consistency required in this study. This implied that subjects' attitudes about health changed over time - a finding which was not totally unexpected given subjects' circumstances. However, it should be noted that a shorter time interval between applications of the questionnaire might have given a better indication of the reliability of the test. Since, this questionnaire already has been shown to be reliable (Wallston et al, 1976) it was assumed that the inconsistency between the 16 week and 38 week responses may have been due to changes of attitude which had taken place during this period. Accordingly, the data produced by this questionnaire has been included in later analyses as a potential outcome measure.

Table 17: Intra-rater Agreement for Questionnaire Two (N=96)

Variable label	Pearson's r
Internal score	0.67
External score	0.57
Total score	0.62

The third questionnaire, the Work and Life Attitude Scale (Warr et al, 1979) was completed by employed people only. Of the 86 subjects in work at the time of their injury, 56 people completed the questionnaire twice. Following the first application of the test, 83% of respondents returned the questionnaire. After the second application of the test this response rate dropped to 65%. However, as is evident from Table 18, an adequate level of positive correlation was demonstrated between the two applications of the questionnaire for the sub-scales concerned with work involvement and life satisfaction. The lowest level of correlation (r = 0.42) applied to the scaling of overall anxiety, while sections covering job satisfaction, overall job satisfaction and higher order need strength demonstrated correlations in the mid to high sixties. Like Questionnaire Two, in the context of this study, this questionnaire elicited insufficiently similar responses from employed subjects at 16 and 38 weeks following injury to be considered reliable. Because of this relative instability, it was assumed that subjects' attitudes about their work had changed over time. However, unlike the former questionnaire, former tests of reliability did not meet the stringent criterion set for this study and, hence, there were no grounds for treating these scales as potential measures of outcome. Therefore, these data have been used for descriptive purposes only.

Table 18: Intra-rater Agreement for Questionnaire Three (N=56)

Variable label	Pearson's r
Work involvement	0.81
Intrinsic job motivation	0.62
Job satisfaction	0.65
Overall job satisfaction	0.69
Life satisfaction	0.75
Overall life satisfaction	0.48
Perceived intrinsic job characteristics	0.57
Higher order need strength	0.66
Self-rated anxiety	0.62
Overall anxiety	0.42
Happiness	0.51

In addition to the three psychological questionnaires, subjects were asked to express their satisfaction with their recovery at the time of each interview. As anticipated, subjects' opinions changed over time, the intra-rater reliability for this variable (N = 97) being r = 0.36. In fact, the time scale between the two interviews (ie 22 weeks) was not a fair test of intra-rater reliability because subjects' attitudes were likely to have changed as their recovery progressed. Indeed, the inter-rater reliability obtained for subjects (N = 7) expressed satisfaction at 16 weeks was found to be reliable (r = 0.87). The reliability of data for the same variable at 38 weeks was not tested because, practical constraints decreed that the fieldworkers worked together for a maximum of six months and this was not long enough to collect data for the final home interviews. Therefore, later analyses are based upon subjects' expressed satisfaction with their recovery at 16 weeks and not 38 weeks. This variable has been used to examine the concurrent validity of certain of the outcome measures discussed later in this chapter.

4.2.3. Clinical data

The following five tables (Tables 19-23) present data derived from a random sample of 15 sets of case notes and x-rays. The author collected clinical data from these 15 cases twice, allowing several months to elapse between the two data collection exercises. The second review was conducted without reference to the first set of data. Quite independently, the other fieldworker collected the same data for the same 15 subjects. Therefore, the next five tables (Tables

19–23) show both intra-rater and inter-rater agreement for clinical variables.

Table 19 gives the percentage agreement obtained for data used to describe characteristics of the initial fractures. Perfect agreement over time as achieved for site of fracture, judged velocity of injury and (for the 11 subjects with tibial fractures) the presence and level of fibular fracture. A high level of intra-rater agreement also was achieved for severity of injury (93%), initial angulation of the fragments (r = 0.91) and the pattern of fracture (87%). The result for the initial displacement of the fracture (73%) just satisfied the required level of consistency (⩾70%) for this study. In fact, the only variable which did not satisfy this criterion for intra-rater agreement was the author's use of Winquist et al's (1980) classification for grading comminuted fractures. Only one of the four comminuted fractures was classified in the same way twice (25% agreement) and, while this number was too small to provide an adequate test of the accuracy of the classification, doubts about the classification were increased by the fact that the two raters agreed upon the coding of only one comminuted fracture (25% agreement).

One other variable in this group produced inconsistent data between raters, namely the coding of velocity of injury. Despite the fact that velocity was coded as "low" or "high", only eight of the 15 cases were coded identically (53% agreement). As with the rating of visual deformity, velocity of injury was based upon judgements which were shown to vary considerably between the two fieldworkers. For the purpose of this thesis, the variables "degree of comminution" and "velocity of injury" have been excluded from later analyses.

Table 19: Intra-rater and Inter-rater Agreement for Initial Fracture Classification Variables (N=15)

Variable label	Intra-rater agreement % (r)	Inter-rater agreement % (r)
Severity	93	100
Grade of compoundness	93	100
Site	100	86
Angulation	N/A (0.91)	N/A (0.91)
Initial displacement	73	73
Pattern of fracture	87	87
Degree of comminution*	25	25
Velocity of injury	100	53
Fibular fracture**	100	93
Level of fibular fracture**	100	93

* N=4
** N=11
N/A not applicable

Tables 20 and 21 demonstrate the good agreement obtained for intra-rater and inter-rater results for the coding of injuries associated with the fracture and for injuries sustained in other areas of the body. Part of the explanation for these favourable results was that few subjects experienced minor secondary injuries.

Table 20: Intra-rater and Inter-rater Agreement for Associated Injury Variables (N=15)

Variable label	Intra-rater agreement %	Inter-rater agreement %
Skin deficit	93	93
Neurological deficit	100	93
Tendonous injury	100	100
Ligamentous injury	100	100
Vascular injury	93	100
Other injuries	100	93

There were very few instances of subjects sustaining injuries associated with the fracture, itself, and patients with multiple injuries were excluded from the study (see Chapter 3.2). Hence, these variables were reliable because they were inappropriately sensitive to the presenting condition of subjects.

Table 21: Intra-rater and Inter-rater Agreement for Other Injuries (N=15)

Variable label	Intra-rater agreement %	Inter-rater agreement %
Head	100	100
Ipsilateral arm	93	93
Contralateral arm	100	100
Ipsilateral leg	100	100
Contralateral leg	100	100
Spine	100	100
Pelvis	100	100
Other injury	100	100

The treatment variables included in this study considered the first three treatments undergone by subjects and the number of days or weeks following injury when these had taken place. Where a subject was treated in an external cast, the week post-injury when the cast was removed was recorded. Over time, the percentage agreement achieved for all the treatment variables exceeded the 70% criterion. The author coded 12 of the 15 subjects in the same way twice for their initial treatment.

Discrepancies occurred for the following reasons. One older woman with a femoral fracture was recorded as having been treated conservatively, in traction, prior to internal fixation on one occasion, whilst on the other occasion she was recorded as having undergone internal fixation 14 days following injury as her first treatment. This one case alone accounted for the low correlation co-efficient of $r = 0.16$ for the number of days to initial treatment. The other two cases were subjects who were coded as having had their leg placed in a cast without manipulation under anaesthetic on one occasion, whereas on the other occasion they were coded as having had their fracture manipulated under anaesthetic.

Table 22: Intra-rater and Inter-rater Agreement for Treatment Variables (N=15)

Variable label	Intra-rater agreement % (r)	Inter-rater agreement % (r)
Treatment 1	80	60
Days to treatment 1	93 (0.16)	67(-0.16)
Treatment 2	93	73
Weeks to treatment 2	93 (0.85)	73 (0.32)
Treatment 3*	87	100
Weeks to treatment 3**	100 (1.00)	100 (1.00)
Week cast removed*	100 (1.00)	100 (1.00)

* N=14
** N=13

The above differences accounted for discrepancies in recording data for the second and third treatments as well. Nevertheless, the intra-rater agreement for all these treatment variables was sufficiently high to have satisfied the requirement set out for this study. This was not so for the consistency of treatment data between fieldworkers. Only nine of the 15 subjects (60% agreement) were recorded as having undergone exactly the same initial treatment procedure by both raters. Four of these discrepancies were attributable to whether or not subjects, whose legs were immobilised in a cast, had had their leg manipulated under anaesthetic. The other two cases differed because one rater recorded that they had had their fractures internally fixed, while the other had recorded that they had been placed in traction with internal fixation noted as their second treatment procedure. Both subjects had sustained femoral shaft fractures. While the ultimate treatment methods undergone by subjects were not in question between the raters, the way in which this information was recorded clearly was inconsistent. For this reason, data concerning treatment methods probably is best collected by one person or else it should be collected following stringent rules of coding if two or more fieldworkers have to produce comparative data. As one fieldworker collected data for the main series of subjects described in this thesis, treatment variables have been included in later analyses. However, it may not be justifiable to compare these data with the sequence of treatment methods described elsewhere.

Finally, attempts to collect data from hospital notes describing the various stages of weight bearing in weeks met with mixed success (see Table 23). The week in which subjects were recorded as being mobile, up non-weight bearing was equivocal for data collected over time and between raters. However, the week in which subjects started partially-weight bearing was less contentious and produced consistent intra-rater (r = 1.00) and inter-rater (r = 0.98) results. The inter-rater agreement for the week in which subjects were fully-weight bearing (r = 0.71) produced a more consistent result than for the same information recorded by one rater over time (r = 0.68). Part of the reason for the lack of stability of this data was that the stages of weight bearing achieved by subjects were implied rather than explicitly stated in hospital notes. For example, statements such as "We are going to put this right ankle into a below knee walker so that he can start touch-weight bearing" inferred that the patient was about to start partially weight bearing, but was actually either on bed rest or non-weight bearing at the time of dictation. Similarly, the interpretation of audio tapes by secretarial staff further confused the issue. For example, the following sentence was found in one subject's notes:

> "I think we should continue non-weight bearing, partially-weight bearing as he is already putting full weight through when transferring."

Clearly, this was a transcription error between dictation and typed script, and not a record of the clinician's actual words. Nevertheless, extracting reliable data from such information proved impossible for time to non-weight bear and fully weight bear and so these variables have been omitted from further consideration.

Table 23: Intra-rater and Inter-rater Agreement for Mobilisation Variables from Hospital Notes

Variable label	N	Intra-rater agreement r	er Intra-rater agreement r
Week non-weight bearing	15	0.58	0.29
Week partial weight bearing	11	1.00	0.98
Week full weight bearing	9	0.68	0.71

4.3. The Evaluation of Potential Dependent Variables

Seven dependent variables were singled out as potential measures of outcome (see Chapter 3.4) and these were: time to union, incidence of complications, incidence of malunion, range of joint movement, return to work, resumption of activities and functional ability.

Each of these dependent variables will be discussed in relation to the concepts of sensitivity, validity and reliability (see Chapter 2.2).

4.3.1. Union measures

The determination of union and the time taken for a fracture to unite have been two of the most influential variables in measuring outcome following fracture and, therefore, it was of importance to discover that the intra-rater and inter-rater information extracted from subjects' hospital notes with respect whether or not a fracture had united was found to be consistent (see Table 24).

Table 24: Intra-rater and Inter-rater Agreement for Union Variables

Variable label	N	Intra-rater agreement % (r)	Inter-rater agreement % (r)
Union	15	87	93
Weeks to union	11	N/A (1.00)	N/A (0.29)

N/A not applicable

However, it is appropriate to re-iterate that most fractures unite eventually (see Chapter 1.4) and, therefore, this measure, in itself, was too insensitive to be of much value. The sensitivity of collecting data retrospectively from hospital notes and the validity of using "rate" as a criterion for success have been discussed already in Chapter 2.3. Despite the questionable validity of using "rate", this approach to measurement offered a more sensitive measure of union by incorporating a time scale of weeks or months to union. However, attempts to extract this information from subjects' hospital notes were met with mixed success. On the one hand, the intra-rater reliability of the measure was found to be $r = 1.00$ – in other words, the two sets of data collected by one rater were perfectly, positively correlated. While on the other hand, the inter-rater reliability of the measure was only r = 0.29. This confirmed doubts about the appropriateness of using time to union as a means for comparing the success of different methods of treatment reported in different studies or by different surgeons. Within the context of this study, weeks to union has been employed as a measure of physiological outcome merely on the grounds that these data were shown to provide reproducable data when collected by one fieldworker. However, the validity of this measure will remain in question until it is shown that clinical judgements correlate with an alternative, objective measure of physiological recovery.

4.3.2. Complication rate measures

Ten variables were used to collect data concerning the clinical complications experienced by subjects during the period of their recovery. Because these data had to be collected retrospectively from hospital notes, each variable was rated as a "yes/no" dichotomy creating a scale sensitive to gross changes only. Furthermore, the sensitivity of the measure was affected by the comprehensiveness and accuracy of details documented in each person's records. For example, because each variable had to be scaled on a "yes/no" basis, any mention of the occurrence of a complication - no matter how trivial - had to be noted as "yes". Thus, superficial infections could not be distinguished from deep infections and a slight displacement of fragments had to be given equal importance to a major displacement because such qualitative detail was not recorded routinely in the hospital notes.

The validity of using the incidence of complications as a measure of success has been discussed earlier (see Chapter 2.3). In this respect, it was likely that cases of compartment syndrome, ischaemic contracture and delayed union reflected the severity of the initial injury rather than having arisen as a consequence of the treatment methods being used and so it was debatable whether they contributed to or detracted from the validity of the measure. Nevertheless, this means for reporting one aspect of the efficacy of various treatments has gained general acceptance over the years and, as such, complication rates have face validity as a measure of outcome.

Relatively speaking, complications were rare occurrences following fracture and, therefore, it was unlikely that they would occur in sufficient numbers to be of value in statistical analyses. Yet, because they occurred so infrequently, it was all the more important that cases were noted and reported accurately. Table 25 shows the intra-rater and inter-rater agreement for reporting complications experienced by 15 subjects. It is evident from this table that, whilst reports over time and between raters were consistent (the agreement attained for all variables exceeding the 70% criterion required for this study), these high percentages reflect the consistency of reporting the **absence** of complication rather than the converse.

Table 25: Intra-rater and Inter-rater Agreement for Complications (N=15)

Variable label	Intra-rater agreement %	Inter-rater agreement %
Compartment syndrome	93	100
Ischaemic contracture	93	100
Skin problems	80	100
Clinical infection	93	87
Shift/angulation	87	80
Refracture	93	93
Delayed/non-union	93	93
Venostasis	93	100
Oedema	80	100
Other complications	80	93

In other words, percentage agreement inflated the accuracy of reporting complications because a single case of infection, for example, cited on one occasion and not on another would have resulted in 93% agreement even though, in another sense, it could have been interpreted as 100% disagreement. For this reason, caution should be applied when interpreting the incidence of complications as a measure of outcome.

4.3.3. Malunion measures

For the purpose of this study, malunion was considered from four perspectives. Where the bone fragments overlapped on the final x-ray, the extent of this overlap was measured in centimetres. Valgus angulations were measured to the nearest degree from each subject's latest AP x-ray. Varus angulations were measured similarly. Finally, each rater made a subjective judgement about the presence or absence of malunion, taking into consideration the appearance of the fracture on both the AP and lateral views of their latest x-rays.

In practice, the sensitivity and validity of measuring the extent which fragments overlapped from an x-ray was questionable since the magnification of the x-ray will have affected measurement (see Table 26). Needless to say, data obtained in this way was consistent, there being 93% agreement for data collected over time and 87% agreement for data collected by different raters. However, there was some question as to whether the overlap of fragments on x-ray signified measurable shortening of the limb. In fact, no relationship could be found between the measurement of limb shortening taken during examination and the measurement of overlap from the x-rays ($r = 0.01$, $N = 71$, $p = 0.46$). By contrast, valgus and varus measurements were not affected by the magnification of the x-rays. Yet, whilst these measurements were shown to be consistent when taken by one rater (valgus, $r = 0.79$; varus, $r = 0.72$), they were insufficiently consistent between raters (valgus, $r = 0.39$; varus, $r = 0.57$). This signified that the technique was at fault and not that one rater was better at taking the measurements than the other. Nevertheless, the implication of this may be that such measures could be used to evaluate outcome in the context of a single study where one fieldworker gathered the data, but perhaps should not be used to compare results between studies or where two or more fieldworkers had collected data.

Table 26: Intra-rater and Inter-rater Agreement for Malunion Variables

Variable label	N	Intra-rater agreement % (r)	Inter-rater agreement % (r)
Fragment overlap	13	93	87
Valgus	14	N/A (0.79)	N/A (0.39)
Varus	14	N/A (0.72)	N/A (0.57)
Malunion	15	93	47

N/A not applicable

This finding also applied to the subjective evaluation of malunion. The intra-rater agreement obtained for this variable was 93% agreement, compared with 47% agreement between raters. This finding reaffirmed the fact that opinion-based data had dubious properties of measurement. Despite the fact that the sensitivity of the variable was necessarily crude (a decision being made between the presence or absence of malunion) eight of the 15 subjects whose x-rays were reviewed were rated differently by the two fieldworkers.

In summary, data collected in relation to the incidence or degree of specific types of malunion should be interpreted with care and should not be used for the basis of comparisons between studies.

4.3.4. Joint range measures

Goniometric measures of joint range were recorded to the nearest degree, thus providing what appeared to be a highly sensitive scale of measurement. However, the accuracy of the method adopted for monitoring knee and ankle joint range (see Chapter 3) also influenced the accuracy of the data. Both knee and ankle ranges were divided into component aspects of flexion and extension (dorsiflexion or plantarflexion with respect to the ankle). In order to assess the properties of measurement of the instrument and procedures, repeat measures were taken from subjects' unaffected limb. These are displayed in Table 27. As may be seen from this table, the reliability of data relating to ankle measures proved very unreliable over time and between raters. For the intra-rater reliability co-efficients, this meant that the 95% confidence intervals (CI) when N = 70 were as follows for measurements of the ankle joint:

- dorsiflexion $r = 0.33$ gave a CI of $\pm 10^{\circ}$
- plantarflexion $r = 0.35$ gave a CI of $\pm 15^{\circ}$

In other words, increased movement in the affected joint would have had to have exceeded these values in order to be attributed to real change in the joint as opposed to measurement error. The accuracy of measurements taken for the knee were found to be consistent between raters, but not over time. This was an unexpected finding since most authors (eg Norkin et al, 1985) acknowledge the inconsistency of the technique whilst claiming that its intra-rater reliability tends to be better than its inter-rater reliability.

Table 27: Intra-rater and Inter-rater Agreement for Range of Movement in Unaffected Limb

Variable label	N	Intra-rater agreement r	N	Inter-rater agreement r
Knee flexion	89	0.65	6	0.72
Knee extension	89	0.32	6	0.80
Dorsiflexion	70	0.33	5	0.06
Plantarflexion	70	0.35	5	0.44

Nevertheless, corresponding 95% confidence intervals for the intra-rater correlation co-efficients when N = 89 were as follows for measurements of the knee joint:

- knee flexion r = 0.65 gave a CI of $\pm$ 8°

- knee extension r = 0.32 gave a CI of $\pm$ 3°

The inter-rater agreement achieved between raters for measurements taken from the affected limb during the same week are shown in Table 28. These were demonstrated to be consistent between raters. This may indicate that the variation for measures taken after in interval of five months might have reflected real changes taking place in the unaffected joint rather than the author's inability to replicate the measurements.

Table 28: Inter-rater Agreement for Range of Movement in Affected Limb

Value label	N	Pearson's r
Knee flexion	6	0.95
Knee extension	6	0.83
Dorsiflexion	5	0.81
Plantarflexion	5	0.71

Goniometry is considered to be a valid means of assessing joint mobility and has long been used for this purpose (see Chapter 2.3). However, it is clear from the above results that changes in joint range, for the better or worse, are meaningful only when they exceed the bounds of error known for individuals taking repeat measurements of a stable situation. Without this knowledge, fluctuations of joint range are likely to be due to fluctuation in operator performance and not joint performance. Furthermore, the accepted way for expressing the adequacy of joint range is in relation to the corresponding joint on the ipsilateral limb (see Chapter 3.4). If the accuracy of this normative standard is in question, then the technique for measuring outcome will be all the more dubious. Thus, in the context of this research, joint range measurements have been used to report reduced movement in the affected limb only when the reduction exceeded the error of measurement calculated for the 95% confidence intervals for each direction of movement.

4.3.5. Return to work measures

Return to work as a measure of rehabilitative outcome following lower limb fracture was relevant only to those subjects who were in employment at the time of injury. Thus, this variable was sensitive to the gross changes taking place for a sub-section of the patient population, albeit the majority of subjects (77%). However, for the remaining 26 (23%), subjects, the variable provided descriptive data (by recording whether or not subjects remained unemployed), but not outcome data. For example, in those instances where subjects were formerly unemployed, but were successful in finding themselves a job by the end of the study, there were no grounds for using the variable as a measure of success. Clearly, the fact that subjects found employment had not come about because of treatment they had received for their fracture.

Where relevant, data describing return to work was collected in two ways. The least sensitive measure was provided by recording whether or not subjects had returned to work at the time of their 16 week and 38 week interviews. In addition to this detail, subjects were asked the exact date of their return and this was converted into the number of weeks post-injury that they said they had resumed work. For subjects who were still off work 38 weeks following injury, this latter method of recording ratio data, while being more sensitive, posed a problem because their week of return was unknown. Similarly, people who were made redundant whilst off sick had to be excluded from the analysis of ratio data. So, although return to work measured in weeks was more sensitive to change than ordinal data collected at the time of the home interviews, it was subject to a greater amount of missing data, either due to the reasons outlined above or because subjects could not remember their date or week of return.

The validity of return to work as a measure of recovery has been questioned (see Chapter 2.4) because it is likely to be influenced by factors other than recovery. For example, there were instances where the loss of a job or the timing of return were independent of recovery. One case in point was a motor mechanic who gave in his notice whilst awaiting confirmation that he had been accepted into the Army. At the time of interview he was unemployed, but this fact neither reflected his ability to work, nor represented the loss of a job through injury. Generally, however, redundancies and early retirals occurred as a direct result of injury. It was also recognised that the validity of this variable was likely to be affected by the type of work being undertaken by subjects. In fact, a significant association was found between social class (coded in accordance with the OPCS, 1970) and weeks to return to work (rho = 0.27, N = 65, p = 0.02). Thus, the less skilled a worker, the longer the time it took him or her to return to work. By contrast, no relationship was found between time to union and time to return to work (r = 0.05, N = 48, p = 0.38), nor between subjects' expressed satisfaction with their recovery at 16 weeks post-injury and the timing of their return to work (r = 0.05, N = 63, p = 0.35). So, although this variable had face validity in the sense that subjects and clinicians, alike, judged it to be an important end point of recovery, as a measure of outcome it is debatable whether time to return to work was a valid test of recovery or a function of other influences.

The inter-rater consistency of data derived from recording whether or not subjects had returned to work 16 weeks following injury has been established already (see Table 13). Since it was not feasible to collect data for the 38 week interview, the reliability of the timing of return was tested against whether or not subjects were back at work by their 16 week and 38 week interview. In either case, the variable "weeks to return to work" was divided into a binomial variable. For example, the employment outcome at 16 weeks coded as "still off" work or "returned" to work was correlated with weeks to return group as "0-16 weeks" and "17 weeks and over". The correlation co-efficient for these data was phi = -0.97 (N = 62) while that for data relating to the 38 week interview was phi = -0.82 (N = 62). In both cases, the gross reliability of the data was confirmed in relation to the criterion set for this study (0.70). The reason for the negative co-efficients was due to the direction of scaling and not the existence of an inverse relationship between the two methods of recording return to work.

4.3.6. Activity measures

As already stated, recovery was perceived by patients in terms of resumption of activity (see Chapter 2) and ADL type scales were insensitive to the types and frequency of involvement in activity performed by patients with lower limb fractures. Therefore, alternative measures were required which would offer a more sensitive scale. The scale selected was a four-point ordinal scale which graded participation in terms of: never, less than once per week, once per week and more than once per week. This scale was applied to specified social activities, transport usage and sports involvement and whilst the scale appeared to be appropriate for a number of these variables (judged by the finding that all points on the scale were being used), it appeared to be inappropriate for others. For example, for certain variables, all subjects either reported that they never or that they infrequently participated in the particular activity (eg attending appointments, riding a moped or skiing). As with the return to work variable, such scales were specific to sub-groups of the patient population who were involved in these activities in the month prior to interview. So, while all subjects were initially rated as participating in at least one social variable, 12 subjects reported that they had not used any form of transport as a passenger over the preceding month, 39 subjects had not driven a vehicle and 48 subjects had not played sport. Obviously, the sensitivity of scales relating to driving were inappropriate for non-drivers. Similarly, the recovery of non-sportsmen and women was not monitored by scales referring to participation in sport.

Nevertheless, most of the subjects in the series saw the activities covered by the frequency tables as legitimate types of activity for people of their age and with their kind of injury. Therefore, while it may be claimed that these activity measures had face validity, testing the validity of such scales was beyond the scope of this study.

The reliability of the scales was assessed for data collected during admission interviews and the first follow-up interviews. Tables 29 and 30 summarise the results of tests of reliability on data derived from the variables enquiring about frequency of social activities such as shopping, visiting friends/relations and visiting clubs or public houses. From Table 29, it may be seen that these first three items were found to be consistent over time and between raters for reports concerning pre-injury activity. (In each case Spearman's rho exceeded 0.70.) The remaining items were found to produce inconsistent results or, in the case of frequency of attending entertainments, were consistent only when applied by the same rater. The "other" category for all the activity groups of variables was shown to be superfluous or, when used, highly unreliable.

Table 29: Intra-rater and Inter-rater Agreement for Pre-injury Frequency of Social Contact

Variable label	Intra-rater agreement rho*	Inter-rater agreement rho**
Shopping	0.84	0.83
Visiting	0.80	0.88
Clubs/pubs	0.91	0.84
Leisure pursuits	0.08	0.23
Appointments	0.33	0.42
Entertainment	0.94	0.59
Other	-	-0.33

* N=12
** N=9

Following injury, only two of the three items found to be consistent for pre-injury activity remained so between raters (see Table 30). These were reports of frequency of visiting friends/relations (rho = 0.75) and visiting clubs/pubs (rho = 0.86).

Table 30: Inter-rater Agreement for Frequency of Social Contact at 16 week Follow-up (N=7)

Variable label	Spearman's rho
Shopping	-0.35
Visiting	0.75
Clubs/pubs	0.86
Leisure pursuits	-0.78
Appointments	0.04
Entertainment	0.56
Other	-0.25

Equivalent tables for use of passenger transport are featured in Tables 31 and 32. Subjects rarely reported being passengers on mopeds or in other types of transport and this lack of data meant that correlation co-efficients could not be computed for these variables. With the exception of the inter-rater agreement for subjects reported use of trains, other reports of pre-injury usage were consistent over time and between raters (see Table 31).

Table 31: Intra-rater and Inter-rater Agreement Pre-injury Frequency of Using Passenger Transport

Variable label	Intra-rater agreement rho*	Inter-rater agreement rho**
Bus	1.00	0.80
Train	1.00	0.66
Moped	-	-
Motorbike	1.00	1.00
Car	0.84	0.80
Other	-	-

* N=12
** N=9

Following injury, only reports of the use of transport as a passenger were reliable for motorcyclists (rho = 1.00) and car users (rho = 0.88) - see Table 32.

Table 32: Inter-rater Agreement for Frequency of Using Passenger Transport at 16 week Follow-up (N=7)

Variable label	Spearman's rho
Bus	0.10
Train	-0.04
Moped	-
Motorbike	1.00
Car	0.88
Other	-0.26

A similar situation arose for drivers' reported use of vehicles, "driving" being defined as anyone in control of a vehicle whether a bicycle or lorry. The majority of drivers used either a motorbike or car. Although the intra-rater reliability of frequency data for the reported use of motorbikes prior to injury proved to be inconsistent (rho = 0.28), these data were stable between raters (rho = 1.00). Equivalent co-efficients for car drivers were consistent for intra-rater agreement (rho = 0.72) and inter-rater agreement (rho = 1.00) - see Table 33.

Table 33: Intra-rater and Inter-rater Agreement for Pre-injury Frequency of Driving

Variable label	Intra-rater agreement rho*	Inter-rater agreement rho**
Bicycle	0.41	-
Moped	-	-
Motorbike	0.28	1.00
Car	0.72	1.00
Other	-	0.48

* N=12
** N=9

At the 16 week follow-up interview, data gathered from motorcyclists and car drivers again was shown to be consistent (rho = 0.78) - see Table 34.

Table 34: Inter-rater Agreement for Frequency of Driving at 16 week Follow-up (N=7)

Variable label	Spearman's rho
Bicycle	0.17
Moped	-
Motorbike	0.78
Car	0.78
Other	1.00

Finally, of the 64 subjects who played sport, the majority were football players with a minority of subjects involved in racket sports (such as squash or tennis), contact sports (such as tae-kwon-do) and skiing. As can be seen from Table 35, the reliability of other variables could not be ascertained because no subjects in the sample played these sports. However, the frequency data for playing football and racket sports prior to injury was consistent over time and between raters. Not surprisingly, no-one in the sample series resumed playing sport at 16 weeks.

Table 35: Intra-rater and Inter-rater Agreement for Pre-injury Frequency of Playing Sport

Variable label	Intra-rater agreement rho*	Inter-rater agreement rho**
Rugby	-	-
Football	0.96	0.97
Skiing	-	1.00
Contact sport	1.00	-
Racket sport(1)	1.00	0.88
Racket sport(2)	-	-
Ball games	-	-
Other games	0.52	0.28

* N=12
** N=9

In summary, only eight of the activity measures were shown to produce reliable data for both reported pre and post-injury activity. These eight variables were:

- visiting friends/relations
- visiting clubs/pubs
- passenger use of transport
- passenger use of cars
- drivers of motorbikes
- drivers of cars
- participation in football
- participation in racket sports

Accordingly, only these variables have been discussed in the following chapters.

4.3.7. Functional ability measures

Finally, the measurement of functional ability was founded upon a number of basic postures and movements relevant to the functioning of lower limbs. These variables were derived from the ability assessment developed as part of the Activity Matching Ability System (AMAS) and evaluated within the Scunthorpe Works of the British Steel Corporation (Sinclair et al, 1984). The sensitivity of the instrument was considered in terms of its coverage of functions and the scaling of each item. Twenty-one variables were used to collect functional data and each was rated in terms of the need to maintain or perform the relevant position or movement relative to a subject's work or pastime activities. Therefore, items which were reported as unnecessary for a majority of subjects were insensitive to the functional abilities of the patient population. Variables which fell into this category included transfers from the sitting position to the ground which were not applicable for 78 subjects; the use of foot controls (other than for driving) which were not applicable for 84 subjects and foot actions which were not applicable for 91 subjects.

For those variables which were reported to be necessary functions in the context of a subject's work and/or pastimes, each was rated on an ordinal three-point scale according to whether the person reported that they were able to perform the function, could perform it with difficulty, or were unable to perform the function at all. This produced a crude ordinal scale of ability which was capable of singling out people who were experiencing problems with particular positions or movements relative to their needs. So, while the reasons for reduced ability or inability were not specified, people who had no requirement to kneel or run, for example, were not encouraged to obtain an absolute level of ability superfluous to their usual behaviour.

The content validity of the original AMAS items had been assured by including items from a variety of sources and checking these in relation to classifications of function (WHO, 1980) and functional activity scales. Furthermore, the empirical validity of all variables had been assessed in terms of the ability of disabled people, in post, to perform the functions required of them to carry out their jobs. Thus, the validity of the sub-set of variables included in this study had been assessed as part of a broader evaluation (Sinclair et al, (1984).

The reliability of this approach to measuring functional ability was tested item by item for subjects' accuracy of reporting functional need and for the consistency of data reporting ability.

Table 36 summarises the intra-rater and inter-rater agreement for the nominal data relating to subjects' reported need to perform various functions prior to injury, either for their work or for other reasons. Six items attained the 70% level of consistency specified in this study for both intra-rater and inter-rater consistency, respectively, and these were: stooping/crouching (77%, 71%); extensive walking (73%, 71%); running (75%, 71%); climbing stairs (83%, 71%); transfers from sitting to standing (76%, 71%) and the use of private transport (77%, 71%). A further six variables demonstrated intra-rater consistency and these were negotiating slopes/gradients (71%); crossing difficult ground (76%); climbing ladders (77%); the use of public transport (74%); the use of foot controls (71%) and foot actions (88%). In addition, three variables were shown to have inter-rater consistency and these were: the need to adopt awkward postures (71%); kneeling (71%) and jumping (100%). Of these 15 items, the two variables concerned with the use of foot controls and foot actions were known to be insensitive and so these were excluded from further consideration. This resulted in a list of 13 variables which had the potential of producing relatively consistent needs-based data.

Table 36: Intra-rater and Inter-rater Agreement for Pre-injury Need to Perform Functional Movements (nominal data)

Variable label	Intra-rater agreement* %	Inter-rater agreement** %
Awkward postures	59	71
Prolonged: standing	66	43
sitting	59	43
kneeling	63	71
Stooping/crouching	77	71
Extensive walking	73	71
Slopes/gradients	71	57
Crossing difficult ground	76	57
Running	75	71
Jumping	68	100
Climbing: stairs	83	71
ladders	77	43
natural objects	61	29
Lifting/carrying	66	43
Transfers: sit/stand	76	71
stand/crouch	61	43
sit/ground	68	43
Transport: public	74	43
private	77	71
Foot/leg: controls	71	-
actions	88	29

*N=97
**N=7

In conjunction with this information, subjects were asked to report their ability to perform required functions and this data was collected by two raters for seven subjects. Six of the 13 items identified above were found to produce reliable reports of ability and these were the ability to: adopt awkward postures (rho = 0.94); kneel (rho = 0.78); negotiate slopes/gradients (rho = 0.73); cross difficult ground (rho = 0.80); jump (0.96) and climb ladders (rho = 0.94). Of the other seven variables, four were considered to be sufficiently important to retain even though the inter-rater reliability for these variables fell short of the 0.70 criterion. These variables were the ability to: stoop/crouch (rho = 0.63); walk extensively (rho = 0.65); run (rho = 0.65) and climb stairs (rho = 0.65). This decision was taken on the basis that data from only seven subjects could be used for this exercise. As can be seen from Table 37, the four variables mentioned above were markedly more reliable than all but the item concerned with transfers from standing to crouching (rho = 0.73) which was excluded because subjects were unable to report their pre-injury need to perform this function sufficiently uniformly. The remaining three of the 13 variables shown to elicit consistent needs-based data, were too insensitive or unreliable at this stage to consider retaining. These were the ability to: transfer from sitting to standing (inadequate data) and the use of public (rho = -0.30) and private (rho = 0.26) transport.

Table 37: Inter-rater Agreement for Ability to Perform Required Functional Movements at 16 week Follow-up (ordinal data)

Variable label	Inter-rater agreement %	(rho)
Awkward postures	86	(0.94)
Prolonged: standing	43	-
sitting	43	-
kneeling	86	(0.78)
Stooping/crouching	57	(0.63)
Extensive walking	86	(0.65)
Slopes/gradients	86	(0.73)
Crossing difficult ground	67	(0.80)
Running	86	(0.65)
Jumping	86	(0.96)
Climbing: stairs	86	(0.65)
ladders	86	(0.94)
natural objects	43	(0.25)
Lifting/carrying	57	(0.17)
Transfers: sit/stand	86	-
stand/crouch	57	(0.73)
sit/ground	43	-
Transport: public	57	(-0.30)
private	57	(0.26)
Foot/leg: controls	0	(-0.56)
actions	14	(-0.15)

In summary, six of the original 21 items were shown to be sufficiently sensitive and reliable to be used in later analyses. A further four variables satisfied all but tests for the reliability of self-reported ability. These four variables have been retained for use in the later analyses for the reasons stated earlier.

4.4. Summary and Conclusions

The confidence placed upon the accuracy of information reported in any study depends upon the methods and procedures adopted by the research team. Attempts were made when designing this study to standardise and specify methods of data collection in such a way as to produce reliable data for all variables. The extent to which this was achieved has been reported in this chapter in relation to a criterion which required that two separate, independent recordings of the same thing agreed with one another for at least 70% of the responses recorded between raters and/or over time or, alternatively, resulted in a correlation coefficient of at least 0.70. Only eight independent variables did not meet this requirement and these have been omitted from further discussion of the data. These were:

- whether or not subjects had dependents and the type and number of dependents (Table 10).
- overall resumption of social activities (Table 15).
- overall resumption of hobbies (Table 15).
- raters' opinion of the visual deformity of the fractured limb (Table 16).
- degree of comminution (Table 19).
- raters' assessment of velocity of injury (Table 19).
- week to non-weight bear (Table 23).
- week to fully-weight bear (Table 23).

A further nine of the 11 sub-scales for Questionnaire Three also fell short of this criterion, but have been included in the next chapter for descriptive purposes only since it had been claimed that these scales produced relatively consistent psychological data.

In addition to testing the reliability of data collected for all variables, one of the aims of this study was to select and test instruments which could be used to measure physiological, socio-economic, psychological and functional outcome for future experimental research. Seven dependent variables were considered in this way.

The three main clinical measures, namely time to union, complication rates and the incidence of malunion, were demonstrated to have limited use as measures of physiological outcome except perhaps when employed in the context of a single study and by the same fieldworker. However, serious deficiencies in the properties of measurement for each of these variables have been identified in earlier discussions (see Chapter 2.3) and as the result of tests of reliability reported in this chapter.

The most serious criticism of measuring joint range was demonstrated in relation to the sensitivity of the technique and its susceptibility to a high degree of measurement error. Since this margin of error for the author ranged from $\pm 3^{\circ}$ for the measurement of knee extention to $\pm 15^{\circ}$ for the measurement of plantarflexion, reductions or improvements in joint range had to exceed these values in order to be considered fluctuations of joint range as opposed to fluctuations in operator performance. Hence, the sensitivity of this instrument, in the hands of the author, was more sensitive for measuring the outcome of knee movements than for measuring ankle movements. This same property would have to be reassessed for different fieldworkers.

Measures of return to work and frequency of performing activities were found to be relatively reliable instruments for measuring socio-economic outcome, but were applicable only to sub-groups of the patient population. In the latter case, eight out of the original 26 items were selected for inclusion as potential measures of activity because only they provided reproducible information pertinent to the patient group. In addition to these measures, subjects' responses to the Health Locus of Control (HLC) scale (Questionnaire Two) and expressed satisfaction with recovery were demonstrated to change over time and may also provide useful measures of outcome. The properties of measurement for the HLC scale have been tested elsewhere (Wallston et al, 1976). The inter-rater reliability of subjects expressed satisfaction with their recovery when asked twice during the same week was sufficiently stable to enable this instrument to be used by different raters.

Finally, as with the activity variables, not all the items identified for monitoring lower limb function were appropriately sensitive or reliable to be considered as measures. Therefore, from the initial 21 items, 10 were selected for this purpose on the basis that subjects were able to provide reproducible responses for their reported need to perform functions (either for their work or elsewhere) and were able to report their ability to perform these with similar accuracy.

Because there is no set way to measure outcome following a tibial or femoral shaft fracture, it is not surprising that no single measure could be identified to fulfil this purpose. Nor is it surprising that it was not possible to identify an ideal instrument in terms of its properties of measurement because even, so-called, "precision instruments" are subject to error. The purpose of this chapter was to examine the magnitude of error associated with each instrument and, by doing so, to indicate the level of confidence which may be placed upon the descriptions and analyses which follow. Hitherto, it has been assumed that, seemingly, factual information reported in the literature has been accurate. However, the evidence brought to bear in this chapter supports the case for standardising and testing the accuracy of all methods of measurement prior to use.

This having been achieved for the work reported here, the following two chapters present the results of the descriptive study and *post hoc* testing upon the data. Chapter 5 provides a description of the patient population, their circumstances of injury, presenting condition, treatment and recovery. Chapter 6 assesses the relationship between certain independent variables and examples of physiological, socio-economic, psychological and functional outcome using univarate statistical techniques. Having presented these results in relation to time to union, return to work, health attitudes (using the total HLC scores) and the ability to kneel, survival analyses were performed to examine the prognostic potential of select variables for determining time to union and time to return to work and to demonstrate the potential of these statistical procedures for evaluating time-to-response data in future clinical trials concerned with recovery following fracture.

CHAPTER 5

RECOVERY FOLLOWING FRACTURE

5.1. Introduction

The purpose of this chapter is to describe the patient population including their circumstances of injury, presenting condition and certain events which marked their treatment and recovery following lower limb fracture. However, before going on to describe the group as a whole, it was necessary to establish that subjects with the two types of injury, namely tibial and femoral shaft fractures, were not so significantly different as to require consideration as two, separate groups. To achieve this end, 17 variables were selected in order to examine possible social, clinical and rehabilitative differences which might have existed between patients sustaining the two types of injury. The results of this exercise are described below, but have been tabled in Appendix III.II.

There were no statistically significant differences found between the tibial and femoral fracture patients in terms of their age, sex or whether or not they were employed at the time of injury. Similarly, no differences were found between their leg of injury nor the severity of their fracture. However, there was a difference identified for the site of injury, distal sites being more common for tibial fractures, while mid-shaft sites were more common for femoral fractures.

The aetiology of fracture also differed between the two types of injury. Significantly more people with femoral fractures had been involved in road traffic accidents which resulted in a proportionately higher number of patients with femoral fractures making personal injury claims. Nevertheless, there was no demonstrable difference found to suggest that alcohol had been implicated in this higher incidence of vehicle related injuries.

Furthermore, no evidence could be found to indicate that one or other of the groups recovered more quickly. At 16 weeks following injury, there was no difference in the stage of weight bearing achieved by each group. Their likelihood of having returned to work 16 weeks and 38 weeks post-injury was the same, as was their ability to run. Similar opinions were expressed concerning each groups' satisfaction with their recovery at 16 weeks and 38 weeks and; finally, no difference was found in the time taken for the two bones to unite.

On this basis, it was decided that tibial and femoral patients were sufficiently similar to be considered as a single group and, consequently, the remainder of this and the following chapter consider the series as a whole. However, throughout the analyses, a check was maintained upon possible dissimilarities between the two types of injury and where appropriate, these differences have been reported in the text.

5.2. Patient Characteristics and Circumstances of Injury

It was anticipated that the series of subjects would consist mainly of young, male football players and motorcyclists because these people were known to be prone to fracturing their tibia or femur (see Chapter 1.3). Yet, how accurate was this forecast in relation to the current series?

In fact, the series comprised 90 (80%) men and 22 (22%) women, all of whom were required to be of working age. The mean age of the men was younger ($\overline{x}$ = 27.4, sd = 11.00) than that for the women ($\overline{x}$ = 34.5, sd = 16.91) - see Table 38.

Table 38: Age by Sex

	Sex		
Age	Male	Female	Total
16 to 20 yrs	28	7	35
21 to 29 yrs	36	5	41
30 to 65 yrs	26	10	36
Total	90	22	112

Chi-square = 2.95, 2 d.f., p = 0.23 (not significant)

During the 14 months of recruitment, the peak months for hospital admissions were March/April and September/October, with the peak time of day being in the mid afternoon ($\overline{x}$ = 15.00, sd = 5.40). Almost two thirds (63%) of patients were admitted to hospital during the hours of 0700 and 1900. Despite this fact, there was a significantly higher number of admissions between the hours of 2000 and 0600 associated (in patients notes) with the consumption of alcohol prior to injury (see Table 39). The busiest days for hospital admissions were at the weekend; Saturday and Sunday emergencies accounting for 50% of admissions.

Table 39: Hour of Admission by Alcohol Consumption

	Alcohol Consumption		
Hour	Not mentioned	Mentioned	Total
07.00 to 19.00	65	6	71
20.00 to 06.00	16	17	33
Total	81	23	104

* 8 missing

Chi-square = 21.82, 1 d.f., p<0.0001 (significant)

Just over half (57%) the subjects were single and just under half (45%) lived at home with their parents. Only 9 (8%) subjects lived alone. Seven (6%) people lived with friends or distant relatives, while the remaining number of subjects (41%) lived with their spouse, with or without children. Approximately half the group (53%) lived in the City of Edinburgh, with a further 45 (40%) people living in the Lothians. Most people (55%) lived in houses and most families reported that they owned their home (55%).

Many subjects (77%) were employed at the time of injury and 36 (42%) of this number worked in skilled manual jobs. In fact, the majority (97%) of working people were employed full-time and undertook some form of manual work (73%). However, 36 (42%) subjects had been employed in their current job for only one year or less ($\bar{x}$ = 5.5, sd = 7.10), the range spanning from 2 weeks to 35 years. Where subjects were living with a spouse or partner, 27 (66%) of the latter were working either full or part-time.

Roughly equal numbers of people had fractured their right (53%) and left (47%) leg. Considerably more people had injured their tibia (80%) as opposed to their femur (20%) and a significantly greater number of people with femoral fractures had been involved in road traffic accidents - RTA's (Chi-square = 13.52, 1 d.f.,p <0.001) and, consequently, were pursuing personal injury claims (Chi-square = 7.65, 1 d.f., p = 0.006) - see Appendix III.II.

Table 40 shows the place of injury for the series as a whole. Together, sports injuries and RTA's accounted for 76 (68%) of all the fractures. Of the latter group, just over a third (39%) were pedestrians, while a slightly higher percentage (44%) were motorcyclists (this figure included three sports injuries resulting from motorcross). Three quarters of vehicle users had been driving at the time of their accident and, hence, had been at the front of the vehicle. In addition, two of the four passengers had been in the front seat of the car they were travelling in. Thus, five of the seven car occupants reported that they had been wearing a seat belt at the time of injury, while the two back seat passengers stated that they had not been wearing a seat belt. The majority of sports injuries were attributable to football and had resulted from one player colliding with another (77%).

Table 40: Place of Injury

Place	Frequency
At home	3
At work	13
Sports injury	35*
RTA	41
Other	20
Total	112

* includes 3 motorcross injuries

The category "other" injuries comprised 16 (80%) people who had slipped, tripped or fallen from heights and four (20%) people whose limbs had been struck by another person or object.

5.3. Personality of the Fractures

While it may be argued that every fracture presented with a unique set of characteristics, it was necessary to summarise these in such a way as to permit description of the entire group and to facilitate statistical analysis. This was achieved by defining discrete categories for various characteristics of the fractures (see Chapter 3.4) and then testing the accuracy of coding for these variables (see Chapter 4.2).

Of the total series of patients, 87 (78%) people sustained a simple fracture, while 25 (22%) sustained a compound fracture - 10 (40%) of whom had a

Grade I, or slight, compound injury. Overall, fractures occurred most frequently in the lower third of the bone (53%). However, there was a significant difference between the tibial and femoral fractures in this respect. More femoral fractures occurred in the middle third of the bone, while the greatest number of tibial fractures occurred distally (Chi-square = 10.98, 2 d.f., p = 0.004) - see Appendix III.II.

There were 13 cases were the AP view of the casualty x-rays for subjects were missing. Of the remaining 99 cases, the bone fragments were angled (in either varus or valgus) at an angle of 5° or less for half (50%) the fractures. The range extended from 0° to 27° ($\bar{x}$ = 6, sd = 6). Displacement about the horizontal plane occurred in 90 (86%) of the 105 cases where this could be measured. This displacement was 50% or less, in relation to the diameter of the cortex, for about half (54%) the displaced fractures and more than 50% displacement in the other half (46%). There was a significant difference in the degree of angulation present, for fractures demonstrating less than 50% displacement, in comparison with those which were displaced 50% or more (Chi-square = 10.99, 2 d.f., p = 0.004). This tendency was for the less displaced fractures to be less angulated (see Table 41) and *vice versa*.

Table 41: Initial Angulation by Displacement

	Displacement		
Angulation	Less than 50% cortex	50% cortex or more	Total
0 - 5	37	13	50
6 - 10	16	14	30
11 - 27	6	13	19
Total	59	40	99*

* 13 missing

Chi-square = 10.99, 2 d.f., p = 0.004 (significant)

The pattern of fracture was known for all but two cases. Comminution was present in 48 of 110 (44%) cases where this data was available. Three subjects had sustained double fractures, while the incidences of transverse (20%), oblique (16%) and spiral (17%) fractures were similar.

Of the 90 subjects with tibial fractures, 62 (69%) people had fractured their fibula as well and three quarters (74%) of this number had broken their fibula within the same third of the bone as their tibial injury. The incidence of other injuries associated with the primary fracture were: three subjects had ruptured a major blood vessel, one subject had sustained ligamentous damage and two subjects had contused or severed their peroneal nerve. The main secondary injuries sustained by subjects are summarised in Table 42.

Table 42: Secondary Injuries Sustained by Subjects

	Injury			
Body segment	Fracture	Dislocation	Concussion	Total
Head	3	N/A	6	9
Ipsilateral arm	3	-	N/A	3
Contralateral arm	2	-	N/A	2
Ipsilateral leg	8	3	N/A	11
Contralateral leg	1	1	N/A	2
Other	1	1	N/A	2
Total	18	5	6	29

N/A Not applicable

As may be seen from this table, the majority of secondary injuries were fractures of the ipsilateral leg - often undisplaced malleolar fractures or metatarsal fractures which were considered likely to pose a lesser problem to subjects' recovery than their tibial or femoral injury.

Sixty-six (59%) subjects were noted as having a past medical history which might have influenced their recovery. (The majority of this number (55%) had experienced former musculo-skeletal problems; a lesser number (32%) had undergone minor surgery; five (8%) people had pre-existing respiratory conditions; two (3%) people were diabetics; one (1%) person had a cardiac complaint and one (1%) person had a psychological condition.) The remaining 46 (41%) subjects had no known medical history of note.

5.4. Treatment and Clinical Result

No attempt was made to standardise the treatment undergone by subjects recruited to this study because patients were under the care of five different Orthopaedic Consultants, each of whom had their own preferred methods of treatment, and, therefore, it would have been difficult to reach agreement in this respect. Thus, the choice and timing of treatment methods was determined by clinical factors alone and so, in order to describe the treatments received by subjects, a record was made of the first three procedures used to reduce and/or stabilise each fracture and the number of days or weeks post-injury when these had been applied.

At the outset of the study, the most popular method of treatment for tibial fractures was conservative management of the fracture in a POP cast (with or without manipulation under anaesthetic) and, initially, this was applied to 69 of the 90 (77%) tibial fracture patients. Ten (11%) of the tibial fractures were placed in an external fixator and 11 (12%) were stabilised by internal fixation. By contrast, nine of the 22 (41%) femoral fractures were treated by immediate internal fixation; 12 (55%) were placed in traction and one (4%) was stabilised in an external fixator.

As can be seen from Table 43, 56 (50%) subjects underwent two or more procedures and 15 (14%) subjects underwent at least three procedures. Not surprisingly, most (87%) of the fractures were stabilised on the day of admission, or the following day (8%). However, exceptionally, certain fractures (5%) were left until the third or fourth day following injury before being stabilised.

Table 43: Primary and Secondary Methods of Reduction and Stabilisation

Procedure	Treatment 1st	2nd	3rd
Cast	26	-	-
MUA and cast	43	-	-
External fixation	11	1	-
Internal fixation	20	26	6
Other (eg traction, gaitor)	12	12	4
Remanipulation and cast	-	8	-
Bone graft	-	9	5
None	-	53	94
Missing	-	3	3
Total	112	112	112

The timing of secondary procedures ranged from one to 32 weeks following injury, but well over one third (41%) were conducted during the first week. For example, 10 (9%) of the femoral fractures initially placed in traction, subsequently were stabilised with an intramedullary nail. In addition, 16 (15%) tibial fractures were treated by internal fixation; nine (8%) tibial fractures were bone grafted, eight (7%) tibial fractures were remanipulated and placed back in a POP cast; one (1%) tibial fracture was placed in an external fixator and 12 (11%) other fractures were transferred into functional braces or gaitors.

Only 15 (14%) fractures underwent a third treatment intervention, the timing of which took place between two to 41 weeks following injury. Another six (6%) tibial fractures were stabilised by internal fixation, five (5%) fractures (four tibial and one femoral) were bone grafted and four (4%) PTB plasters were exchanged for gaitors.

For those fractures treated in a cast, the median time for its removal was 18.5 weeks following injury and the median time for patients to be instructed to partially weight bear was 4.5 weeks following injury.

In the 105 cases where hospital notes could be traced, the incidence of complications documented for the series were: one (1%) case of compartment syndrome, eight (8%) skin conditions, 15 (14%) cases of clinical infection, 15 (14%) fractures which displaced, four (4%) refractures through the new callus and 12 (11%) cases of so-called "delayed" or "non-union". Venostasis was known to have been diagnosed in six (6%) patients and seven (7%) subjects had an oedematous limb at the time of their last clinic appointment.

Although all the fractures went on to unite, it was possible to identify an approximate date which confirmed this event from subjects' hospital notes. These dates ranged from nine to 60 weeks following injury, with a median value of 26 weeks to union ($\overline{x}$ = 28, sd = 13.2). Nevertheless, little confidence can be placed upon the sensitivity of these data because of the method of data collection and the dubious qualities of measures of union (see Chapter 2.3).

Malunion was recorded in 46 (41%) fractures, but, as noted in Chapter 4.3, this finding was based upon subjective judgement which was thought to be unreliable between different judges and, therefore, this finding merely reflected the stringent criteria adopted by the author. Objectively, the overlap of fragments measured from subjects' final x-rays occurred in 15 (13%) cases to a lesser extent than 1 cm, but this measure did not correlate with attempts to assess limb shortening taken from surface measurements of subjects' limbs (tau = 0.01, N = 71, p = 0.46). Only seven (6%) fractures were recorded as having united in 5° or more of valgus, while 18 (16%) fractures had united in 5° or more of varus. Another seven (6%) fractures were noted as being rotated or displaced.

5.5. Stages of Recovery

Data derived from the two home interviews were used to describe subjects' recovery 16 weeks and 38 weeks following injury. As stated earlier (see Chapter 3), the design of this longitudinal study offered a unique opportunity to collect information at specific time intervals across the patient population, so enabling comparisons to be made between subjects at these two stages of recovery.

Of the initial 112 subjects recruited to the study, seven (6%) subjects were lost to the first home interview, while 14 (13%) subjects were lost to the second interview. However, the number of items missing from these two data sets fluctuated because, in some instances, it was possible to substantiate facts about the recovery of subjects from relatives (eg whether the person was still in a PTB plaster); while in other instances, data could not be obtained from interviewees (eg the exact date or week of their return to work). Therefore, in the following sections, statistics have been based on the percentage of responses elicited for each variable, exclusive of missing data. (In most cases this equated to 112 respondents for the admission data, 105 respondents for the 16 week interview data and 98 respondents for the 38 week interview data.)

5.5.1. Mobilisation

At the time of the first home interview, 36 (33%) subjects still had their fractured leg externally immobilised - the majority (67%) of these fractures being in a PTB plaster, with a minority being in a functional brace/gaitor (25%) or a full leg plaster (8%). By the second interview, only four (4%) people had their leg externally immobilised, all of whom had a gaitor or functional brace *in situ* .

Only four (4%) people reported having had any difficulty in walking prior to injury, one of whom habitually used a walking stick. Nevertheless, 16 weeks following injury, 23 (21%) patients still were not taking full weight through their leg and one (1%) person remained unable to do so even 38 weeks following their accident.

Very few (5%) people reported experiencing pain around their fracture site at the time of either home interview. Yet, approximately half (55%) the subjects reported that they experienced pain, at least sometimes, when walking 16 weeks following injury and just over a third (36%) did so, or continued to do so, 38 weeks following injury. No relationship was found between the reported experience of pain when walking 16 weeks following injury and subjects' involvement in a personal injury claim (Chi-square = 1.76, 1 d.f., $p = 0.42$), but significantly more claimants reported pain when walking at the 38 week interview (Chi-square = 12.45, 1 d.f., $p = 0.002$). The corresponding figures for people reporting their experience of pain when at rest, or at night, may be found in Appendix III.II. There was no significant difference found between insurance claimants and non-claimants for these variables at either point in time. Table 44 summarises the overall number of subjects reporting pain when walking at the time of the two follow-up interviews.

Table 44: Reports of Pain when Walking Following Fracture

	Week of Interview	
	16 weeks	38 weeks
Painfree	43	58
Occasional pain	51	31
Always painful	11	9
Missing	7	14
Total	112	112

5.5.2. Employment

Prior to injury, 86 subjects were working but only 22 (26%) of these employees were back at work by their first home interview, although approximately three quarters (76%) of the group had returned to work by their second home interview (see Table 45).

Table 45: Return to Work Following Fracture

	Return to Work	
Work status	16 weeks	38 weeks
Still off	62	16
Returned	22	65
Out of work	13	16
Economically inactive	15	14
Missing	-	1
Total	112	112

Yet, three of the originally employed people had returned to work by their 38th week following injury only to be given notice. These subjects were: a sheet metal worker who had resumed work two months following injury, but was given notice because he had lost so much time; a clerk in a medical bookshop who returned to work six weeks following injury, but was given notice within her three month trial period and an apprentice film laboratory technician who missed the remaining months of his Youth Training Scheme placement. In addition to these three individuals, another seven people, who were still on sickness absence 38 weeks following injury, also knew that they had lost their jobs (see Figure 3). This resulted in a total of 10 (12%) formerly employed people who apparently lost their job as a direct result of their accident.

A further three people, became unemployed for reasons other than their injury. One welder's short-term contract expired. The other two subjects, a labourer and a motor mechanic, handed in their own notice. The labourer decided to move to Ayrshire and the motor mechanic left his job to join the Army. By comparison, only one formerly unemployed person was in employment 38 weeks after his injury. A summary of the people who were still on sickness benefit at the time of their final interview and the availability of their former job is given in Figure 3, together with the details of those people who were no longer on sickness absence, but had been made redundant by this time.

Figure 3: Summary of the Availability of People's Former Jobs 38 weeks Following Injury

Former Job	Place of Injury	Availability of Job
Still on sickness benefit		
catering assistant	caravan site	still available
civil servant	horse riding	" "
fork lift driver	work	" "
machine operator	pub	" "
maintenance technician	RTA	" "
miner	work	" "
miner	work	" "
roof erector	work	" "
storeman	RTA	" "
fork lift driver	RTA	notice given
grocery stacker	sports	notice 2 wks after injury
handyman	RTA	notice 1 wk after injury
IBM operator	RTA	notice when sickness pay elapsed
miner	work	medical retiral
packer	RTA	notice 3 wks after injury
plumber/fitter	RTA	notice 1 wk after injury
No longer on sickness benefit		
film technician	sport	YTS training missed
clerk (medical bookshop)	RTA	returned at 6 wks but given notice
sheet metal worker	RTA	returned at 2 months but given notice

Of those people who were back at work by their final home interview, 32 (49%) were known to have had their job modified in some way in order to facilitate their return and for 8 (12%) of these people this had involved either a temporary or permanent change of post. Eleven (17%) of the people back at work reported that they were still experiencing minor difficulties in performing their job. The types of problems mentioned were as follows: four people found lifting heavy weights a problem; three people had difficulty climbing ladders; three people experienced a problem with kneeling at work and one auxiliary nurse found being on her feet all shift a problem.

Data available for 60 of the subjects who had returned to work by the end of the follow-up period suggested that the majority (67%) felt that the timing of their return had been about right; a minority (10%) felt that they could have returned to work earlier and just over twice this number (23%) felt that they had gone back to work too soon.

The week of return to work was established for 64 subjects and ranged from four individuals who were back at work three weeks following injury to one person who was known to have resumed work 45 weeks following injury ($\overline{x}$ = 20, sd = 9.4). As stated earlier (see Chapter 4.3), it appeared that the less skilled a worker, the longer it took him or her to return to work.

Despite the redundancies noted above and work difficulties voiced by a minority of those employees who had resumed work, no one had been in contact with vocational rehabilitation services at any point during their recovery. Very few people were even aware of the existence of such services and the handful of people who were informed, felt that their circumstances did not justify the involvement of vocational rehabilitation personnel who were perceived as providing a service for "severely disabled" people.

5.5.3. Rehabilitation services

The prescription of physiotherapy treatment following a fracture has been advocated for every patient with a major fracture (see Chapter 1.4). In this study, only five of the 11 (45%) subjects who reported difficulties in performing their work had been referred for therapy and, overall, less than half the series (44%) were known to have attended for physiotherapy as an out-patient (although the majority had been seen by a physiotherapist as a hospital in-patient). That is not to imply that any advantage necessarily would have been derived from such treatment. In fact, 38 weeks following injury, similar numbers of subjects reported that they had difficulty with, or were still unable to perform, functional activities essential to their needs irrespective of whether or not they had attended physiotherapy treatment (see Appendix III.IV). Whilst it may have been that patients referred for physiotherapy functionally were more restricted and, therefore, atypical of the group as a whole, this observation points to the need for **controlled, clinical trials** in order to investigate the efficacy of such treatment for patients with lower limb fractures.

However, it must be emphasised that the design of this study did not allow inferences to be made about the effectiveness of physiotherapy treatment and these results merely demonstrate that neither the treatment nor non-treatment group were functionally superior 38 weeks following injury.

As may be seen from Table 46, the highest numbers of people (76%) were in contact with their family general practitioner (GP) during their recovery, usually to obtain a medical certificate rather than because they had requested a consultation. Apart from physiotherapy treatment and regular clinic attendances, subjects had negligible contact with other rehabilitation professionals.

Table 46: Reported Contact with Rehabilitation Professionals (N=105)

	Week of Interview	
Profession	16 week	38 weeks
GP	74	80
Physiotherapist (Out-patient)	35	46
Sports coach	2	2
Occupational therapist	-	1
Remedial gymnast	-	1
Other (eg alternative medicine)	6	6

Equally, employees reported minimal contact with work personnel during their recovery. Most people reported that they had been in contact with work colleagues (81%); and to a lesser extent line managers (38%) and personnel managers (32%). However, trade union officials were contacted only when a subject had been involved in a work's accident and just seven (9%) employees had reported to their work's medical officer (where such a post existed). Finally, 14 (18%) employees reported that they had been helped by welfare officers, or similar personnel, for the purpose of clarifying their sickness pay entitlement or other welfare rights (see Table 47).

Table 47: Reported Contact with Work Personnel (N=77)

	Week of Interview	
Personnel	16 weeks	38 weeks
Co-worker	62	62
Line manager	29	29
Personnel manager	21	25
Trade Union official	5	8
Occupational health team	2	7
Other (eg Welfare Officer)	14	14

5.5.4. Post-injury activity

Eight variables were shown to have produced sufficiently reliable data to be used to describe and assess subjects' resumption of activities following injury (see Chapter 4.3). Two of these variables were concerned with the social contacts which subjects had made whilst visiting their families or friends and clubs or pubs. Four variables related to subjects' use of motorbikes or cars, either as a passenger or driver. Finally, two variables assessed the resumption of football and racket sports by former players.

Subjects were required to report their participation in the various activities during the month preceding interview and data was collected for the month prior to injury and at two stages thereafter. Each subject reported their frequency of participation in the forementioned activities on a four-point, ordinal scale and the results of these reports are presented in Tables 48 to 55.

As may be seen from Table 48, the frequency with which subjects stated that they had visited the homes of friends or relations differed little between the three interviews. Prior to injury, 93 of the original 112 (83%) subjects reported that they had visited friends or relations during the preceding month and over half (58%) the group said that they had done so more than once per week. At the time of their first home interview, 83 of the 105 (79%) subjects who were interviewed reported having visited friends or relatives during the previous month, while 54 (51%) had done so more than once per week and this pattern of response was maintained for the second home interview, 84 of 100 (84%)

subjects stating that they had visited friends or relations at some time during the previous month, while 58 (58%) subjects said they had done so more than once per week.

Table 48: Frequency of Visiting Friends/Relations during the Previous Month

	Week of Interview		
Frequency	1 week	16 weeks	38 weeks
Never	19	22	16
Less than 1 per week	10	9	11
1 per week	18	20	15
More than 1 per week	65	54	58
Missing	-	7	12
Total	112	112	112

The frequency with which subjects reported that they had visited clubs or public houses during the month prior to interview appears in Table 49. As with the former table, there appeared to be little change in the pattern of reported behaviour for this variable. Before injury, 103 (92%) people said that they had visited clubs or public houses and 75 (67%) subjects reported that they had done so more than once per week. Likewise, at 16 weeks and 38 weeks following injury, the comparable figures were 91 (87%) and 88 (88%) people, respectively, who stated that they had visited a club or public house on at least one occasion and 59 (56%) and 61 (61%) who said they had done so more than once per week.

Table 49: Frequency of Visiting Clubs and Public Houses during the Previous Month

	Week of Interview		
Frequency	1 week	16 weeks	38 weeks
Never	9	14	12
Less than 1 per week	8	13	7
1 per week	20	19	20
More than 1 per week	75	59	61
Missing	-	7	12
Total	112	112	112

Very few subjects reported that they had riden as a pillion passenger on a motorbike, either prior to or following injury. In fact, the percentage of people doing so remained fairly constant for the data collected for the three interviews (see Table 50).

Table 50: Frequency of Using Motorbikes as a Passenger during the Previous Month

	Week of Interview		
Frequency	1 week	16 weeks	38 weeks
Never	101	97	90
Less than 1 per week	5	6	6
1 per week	6	-	2
More than 1 per week	-	2	2
Missing	-	7	12
Total	112	112	112

Likewise, data relating to passenger travel in cars remained fairly constant for the three interviews, as demonstrated in Table 51. Prior to injury 88 (79%) people reported that they had travelled as a passenger in a car during the previous month and 54 (48%) of the group had done so more than once per week. As might be expected, this pattern of usage was maintained for information collected at the 16 week and 38 week interview. Some 86 (82%) people reported travelling in a car prior to their first home interview and 55 (52%) had done so more than once per week. The equivalent figures for travelling in a car prior to the second home interview were 79 (79%) subjects doing so at least on one occasion, while 46 (46%) people said they had been a passenger in a car more than once per week.

Table 51: Frequency of Using Cars as a Passenger during the Previous Month

	Week of Interview		
Frequency	1 week	16 weeks	38 weeks
Never	24	19	21
Less than 1 per week	24	26	25
1 per week	10	5	8
More than 1 per week	54	55	46
Missing	-	7	12
Total	112	112	112

From these data, it would seem that subjects' reported behaviour with respect to these first four activities was either affected minimally or the scheduling of interviews was such that they were insensitive to the changes which may have taken place. For example, subjects may have been virtually house-bound during their first few weeks post-injury, but thereafter were sufficiently mobile to resume certain types of activity. Certainly, by 16 weeks following injury, most subjects appeared to have resumed their pattern of behaviour with respect to their former frequency of participation in social outings and passenger usage of motorbikes and cars.

This was not the case for either vehicle drivers or sports people, as shown in the next four tables (see Tables 52 - 55). Table 52 gives the frequency with which subjects reported that they had driven a motorbike. Before injury, 18 (16%) subjects stated that they had driven a motorbike during the month prior to injury - 17 (15%) more than once per week. Sixteen weeks following injury, only 4 (4%) motorcyclists stated that they had resumed riding a motorbike and, even though this number had doubled to 8 (8%) by the second home interview, there were still less than half (44%) the initial number of motorcyclists who said they were back driving motorbikes 38 weeks following injury.

Table 52: Frequency of Driving Motorbikes during the Previous Month

	Week of Interview		
Frequency	1 week	16 weeks	38 weeks
Never	94	105	96
Less than 1 per week	-	1	4
1 per week	1	-	-
More than 1 per week	17	3	4
Missing	-	3	8
Total	112	112	112

The next table, Table 53, would seem to confirm that drivers were affected similarly in their frequency of driving cars 16 weeks following injury, but had resumed their former frequency of driving 38 weeks post-injury. At the time of recruitment, 57 (51%) subjects reported that they were car drivers and 44 (39%) stated that they had driven a car more than once per week during the preceding month. Sixteen weeks after injury, only 35 (32%) of the group had resumed driving, 26 (24%) doing so more frequently than once per week.

However, by their final interview, 56 (54%) subjects were back driving and 42 (40%) subjects were driving more regularly than once per week.

Table 53: Frequency of Driving Cars during the Previous Month

	Week of Interview		
Frequency	1 week	16 weeks	38 weeks
Never	55	74	48
Less than 1 per week	8	6	5
1 per week	5	3	9
More than 1 per week	44	26	42
Missing	-	3	8
Total	112	112	112

The resumption of sporting activities such as playing football, tennis, squash and other racket games was not covered adequately by the time plan set for this longitudinal study, as is apparent from the results shown in Tables 54 and 55. A total of 44 (39%) football players were recruited to the study and 21 (19%) reported that they usually played more than once per week during the football season. As might be expected, only 2 (5%) subjects were back playing football 16 weeks following injury and by 38 weeks following injury this number had increased to 14 (32%), with just 4 (9%) subjects stating that they were playing more frequently than once per week. While, undoubtedly, this variable was affected by seasonal variations and, so, in principle, it may have been that footballers were not playing football because no matches were being played, in practice, many players considered themselves unfit to play even though their final follow-up interview may have fallen outwith the football season.

Table 54: Frequency of Playing Football during the Previous Month

	Week of Interview		
Frequency	1 week	16 weeks	38 weeks
Never	68	107	91
Less than 1 per week	9	1	6
1 per week	14	1	4
More than 1 per week	21	-	4
Missing	-	3	7
Total	112	112	112

A similar situation occurred for subjects' who reported that they formerly had played racket sports. Prior to injury, 25 (22%) subjects stated that they had played tennis, squash or an alternative racket sport during the month prior to their accident. Most (32%) people reported that they had played occasionally rather than weekly. Nonetheless, just one (4%) person stated that they had resumed this type of sport 16 weeks following injury and only 7 (28%) people were back playing racket sports 38 weeks after injury (see Table 55).

Table 55: Frequency of Playing Racket Sports during the Previous Month

	Week of Interview		
Frequency	1 week	16 weeks	38 weeks
Never	87	108	98
Less than 1 per week	18	-	5
1 per week	5	-	1
More than 1 per week	2	1	1
Missing	-	3	7
Total	112	112	112

Therefore, it is likely that the follow-up period incorporated in this study was too short to monitor the recovery made by the majority of sports people and a longer follow-up period would be required by any study aiming to evaluate the efficacy of various treatment options *viz a viz* the resumption of activities by sports people.

5.5.5. Functional ability

For the purpose of this study, a shortened version of the AMAS ability assessment was used to assess subjects' lower limb function and ten variables were identified which provided sufficiently accurate needs-based information (relative to work or pastime pursuits) and ability data to be employed in this context (see Chapter 4.3).

Table 56 gives the number of subjects who reported that they needed to perform each of the functions and their corresponding ability to do so 16 weeks following injury. In all, 105 subjects were questioned about these variables at the time of their first home interview , but only the data for those people who responded that they **needed** to be able to kneel, run etc. have been included in the table. For the purpose of comparison, the figures in brackets give the percentage of subjects who reported their level of ability relative to their perceived need to perform each function. Thus, the column headed "Need" represents the total number of responses applicable to each variable.

Table 56: Reported Ability to Perform Functional Activities Required for Work or Pastime Pursuits (16 weeks post-injury)

Variable label	Need	Ability		
		Able	Difficult	Unable
Awkward postures	79	20(25)	27(34)	32(41)
Prolonged kneeling	66	16(24)	17(26)	33(50)
Stooping/crouching	95	41(43)	34(36)	20(21)
Extensive walking	97	42(43)	33(34)	22(23)
Slopes/gradients	97	38(39)	51(53)	8(8)
Crossing difficult ground	101	34(34)	49(48)	18(18)
Running	78	4(5)	17(22)	57(73)
Jumping	71	7(10)	7(10)	57(80)
Climbing: stairs	103	77(75)	26(25)	-
ladders	47	14(30)	10(21)	23(49)

( )%

Not surprisingly, the highest percentage of subjects reported that they were unable to jump (80%) or run (73%) 16 weeks following injury. Prolonged kneeling was reported as impossible for 33 (50%) subjects, while climbing ladders (49%) and getting into awkward positions (41%) were prohibited for a substantial minority of people who needed to perform these functions. Climbing stairs was the only function which the majority (78%) of subjects reported they could do without difficulty. Otherwise, at this stage in recovery, between 57% (ie for stooping/crouching and extensive walking) and 95% (ie for running) people reported difficulty with, or the inability to perform, various functions which they needed to be able to perform.

Equivalent data were obtained for 98 subjects, 38 weeks following injury, and these are displayed in Table 57. Once again, the data was needs-based and, hence, responses have been omitted for people who did not require to kneel, run, jump etc.

Table 57: Reported Ability to Perform Functional Activities Required for Work or Pastime Pursuits (38 weeks post-injury)

Variable label	Need	Ability: Able	Difficult	Unable
Awkward postures	80	56(70)	16(20)	8(10)
Prolonged kneeling	61	30(49)	15(25)	16(26)
Stooping/crouching	94	68(72)	19(20)	7(8)
Extensive walking	89	70(79)	14(15)	5(6)
Slopes/gradients	96	70(73)	24(25)	2(2)
Crossing difficult ground	96	61(64)	29(30)	6(6)
Running	86	34(39)	24(28)	28(33)
Jumping	74	31(42)	19(26)	24(32)
Climbing: stairs	98	82(84)	16(16)	- -
ladders	57	42(74)	6(10)	9(16)

( )%

It is evident from this table that far fewer people were reporting an inability to perform various functions at this stage during recovery; the main problems were associated with running (33% unable), jumping (32% unable) and prolonged kneeling (26% unable). However, with the exception of climbing stairs (84% able) and extensive walking (79% able), at least a quarter of those subjects requiring to perform each function were reporting that they were experiencing functional difficulty or inability 38 weeks following injury.

5.5.6. Clinical examination

At the time of each home interview, a number of subjects still had their leg externally immobilised and, therefore, their affected limb could not be examined. Hence, the following descriptions apply to those subjects who were interviewed and whose limb was unimpeded at the time of each follow-up interview.

A total of 105 subjects were seen 16 weeks following injury and, of this number, 73 (70%) fracture sites could be palpated, 16 (22%) of which were reported to be tender. At 38 weeks, 100 patients' limbs were examined and 15 (15%) subjects reported tenderness at their fracture site.

Table 58 gives the circumferential difference measured for subjects' affected versus unaffected limb. Of those patients' limbs which could be measured 16 weeks following injury, 23 (32%) demonstrated a decrease in the girth of the affected limb of 2cms or more. The corresponding figure, 38 weeks following injury, was 17 (18%) of the group with a reduced limb bulk of 2cms or more.

Table 58: Reduction in the Limb Girth Comparing Subjects' Affected and Unaffected Limbs

	Week of Interview	
Reduction	16 weeks	38 weeks
Less than 2cms	49	79
2cms or more	23	17
Missing	40	16
Total	112	112

Real shortening in the length of the affected segment of the lower limb was measured as approximately 1cm for 17 individuals, both 16 weeks and 38 weeks following injury (24% and 18% respectively).

Goniometric measures of the range of movement for the knee and ankle joints were taken for both legs where both joints were unrestricted. On the basis of the error of measurement, reductions in joint movement have been reported for the affected limb only when they exceeded these values in relation to subject's corresponding, unaffected joint (see Chapter 4.3). From Table 59, it may be seen that in excess of one third (41%) of the group demonstrated a reduction of knee flexion 16 weeks following injury (some of whom were in a PTB), but this figure had decreased to 9 (9%) by the time of the final follow-up examination.

Table 59: Reduced Knee Flexion Comparing Subjects' Affected and Unaffected Limbs

	Week of Interview	
Reduction	16 weeks	38 weeks
No (8^o or less)	58	87
Yes (9^o and over)	40	9
Missing	14	16
Total	112	112

As might be expected, knee extention was affected to a lesser extent (see Table 60); 18 (18%) subjects being unable to extend their leg fully 16 weeks following injury, while only one (1%) subject could not do so 38 weeks following injury.

Table 60: Reduced Knee Extention Comparing Subjects' Affected and Unaffected Limbs

	Week of Interview	
Reduction	16 weeks	38 weeks
No (3° or less)	80	95
Yes (4° and over)	18	1
Missing	14	16
Total	112	112

Ankle joint ranges of movement demonstrated a greater degree of measurement error and, therefore, the detection of a reduction in joint range was influenced by this finding. The resultant effect may have been to under report cases of restricted ankle joint movement. Nevertheless, as shown in Table 61, a quarter (25%) of those people with their ankle joint free to move 16 weeks following injury, demonstrated a definite reduction in dorsiflexion and a similar number (18), through lesser percentage (19%), had restricted dorsiflexion 38 weeks following injury.

Table 61: Reduced Dorsiflexion Comparing Subjects' Affected and Unaffected Limbs

	Week of Interview	
Reduction	16 weeks	38 weeks
No (10° or less)	57	77
Yes (11° and over)	19	18
Missing	36	17
Total	112	112

A definite reduction in plantarflexion was established for 12 (16%) subjects 16 weeks following their injury and 9 (9%) subjects 38 weeks following injury.

Table 62: Reduced Plantarflexion Comparing Subjects' Affected and Unaffected Limbs

Reduction	Week of Interview 16 weeks	 38 weeks
No (15° or less)	64	86
Yes (16° and over)	12	9
Missing	36	17
Total	112	112

It was of interest to discover that the reduced range of knee flexion, measured 16 weeks following injury, correlated significantly with subjects' reports of their functional difficulties or inabilities, expressed at the same stage of recovery, for all the functional variables used for this purpose except the ability to climb stairs. These and other associations found between functional ability and reduced ranges of knee and ankle joint movement have been summarised in Appendix III.V.

5.5.7. Psychological data

As noted in the previous chapter (see Chapter 4.2), a total of 13 subjects reported experiencing pain at the time of either their first or second home interview, but no-one reported experiencing pain on both occasions. Thus, because of the lack of data, no attempt was made to analyse responses to Questionnaire One.

Questionnaire Two, the Health Locus of Control, was completed by 103 (92%) subjects at the time of their first home interview and 97 (87%) subjects at the time of their second home interview. For the purpose of reliability testing, the actual score values were used to compute Pearson's correlation co-efficients for each sub-scale. However, in accordance with Wallston et al (1976), median splits were used to classify subjects as having either a low or high internal, external and total score, based upon the I-E and HLC scales respectively (see Chapter 3.4), and these groupings were used for descriptive and analytical purposes.

As evident from Table 63, the resultant median values derived from the two applications of the questionnaire for the sub-scales and total score were all above the mid-point values for each scale. Despite the fact that each subjects' internal versus external orientation may have changed over time (see Chapter 4.2), the median values for the group as a whole for the I-E scales were identical for both applications of the test and there was only one point of difference between equivalent values for the HLC score.

Table 63: Median Values and Ranges for the HLC Scales

Scale	Scale mid-pt	16 weeks* median	16 weeks* range	38 weeks** median	38 weeks** range
I-score	15	17	5-30	17	6-30
E-score	18	22	6-35	22	6-34
HCL	33	39	21-57	40	18-59

*N = 103
**N = 97

The fact that median splits were used to classify subjects into two roughly equally sized groups, on the basis of their test scores, meant that the division into low and high scorers for each scale was relative to the overall responses recorded for the group as a whole. Comparison of these data with normative data (available for the HLC only and based upon means rather than medians) suggested that the fracture patients were more externally directed than college students or community residents in the USA, but less so than older, primarily black, hypertensive out-patients (Wallston et al, *op cit*).

Table 64: Normative Data for HLC Scores

Sample	No	Age range	Median age	HLC x	HLC sd
College students	185	17-49	20	34.5	6.3
College students	94	17-26	18	33.1	5.4
Community residents	101	17-66	35	35.9	7.1
Fracture subjects*	97	16-63	24	39.1	7.3
Hypertensive outpatients	38	26-70	51	40.1	6.2

* at 38 week interview data for subjects recruited to this study

This apparent tendency towards externality perhaps was due to the fact that many subjects were being monitored as out-patients 38 weeks following injury and, therefore, subjects' perceptions of health might have been influenced by their continuing dependence upon medical decisions and opinions(8).

Questionnaire Three, the Work and Life Attitude Scales (Warr et al, 1979) was completed twice by 56 (65%) of the 86 subjects who were employed at the time of injury. A total of 71 (83%) subjects returned this questionnaire following their first home interview, while 58 (69%) subjects did so following their second home interview. Despite the fact that only scores for the work involvement and life satisfaction sub-scales met the reliability criterion set for this study (see Chapter 4.2), the results obtained for all the sub-scales have been compared with normative data collected by Warr and colleagues (*op cit*) for blue-collar male employees working in the UK manufacturing sector. The table for these data appears in Appendix III.VI and the exercise was carried out because it was acknowledged that the reliability criterion of 0.70, initially set to evaluate the reliability of data derived from a small number of subjects in this study, was particularly high in relation to the larger numbers of subjects included in this test.

The means and standard deviations for responses obtained from employees recruited to this study differed by no more than three points, on any of the 11 sub-scales, from results obtained for other blue-collar workers. This result might reflect the fact that many of the subjects recruited to the present series were manual workers and, hence, blue-collar workers too. However, the group means for each of the sub-scales were slightly lower on the second occasion for all but responses to "work involvement" and "happiness" which remained unchanged.

In addition to the three psychological questionnaires, subjects were asked how satisfied they were with their recovery 16 weeks and 38 weeks following injury. A seven-point, Likert-type scale was used to rate each persons' opinion at these two time periods and this scale ranged from "extremely dissatisfied" to "extremely satisfied" (see Table 65). Of the 105 subjects seen 16 weeks following fracture, 23 (22%) responded that, to some extent, they were dissatisfied with their recovery, 11 (10%) people were not sure and 71 (68%) subjects were either "moderately", "very" or "extremely" satisfied with their progress.

Table 65: Subjects' Opinion of their Recovery 16 weeks and 38 weeks Following Injury

Opinion	Week of Interview 16 weeks	38 weeks
Extremely dissatisfied	6	3
Very dissatisfied	4	4
Moderately dissatisfied	13	8
Not sure	11	3
Moderately satisfied	31	23
Very satisfied	31	39
Extremely satisfied	9	18
Missing	7	14
Total	112	112

By the 38th week following injury, a greater number of subjects were registering satisfaction with their recovery and appeared to be more satisfied than they had been previously. Thus, of the 98 subjects interviewed a second time, 80 (82%) people stated that they were satisfied with their recovery and the majority of this number were either "very" or "extremely" satisfied. Only 3 (3%) people were unsure about the progress they were making and 15 (15%) remained dissatisfied with their recovery.

5.5.8. Insurance and household finances

The reliability of variables concerned with insurance and household finances was not assessed formally because it was considered that unnecessary anxiety might have been aroused by repeating this line of questioning. Therefore, where possible, evidence was corroborated from information recorded in each person's hospital notes. In the majority of cases where medical reports had been conducted, evidence recorded in each person's hospital notes supported the facts supplied by the subjects themselves. Unfortunately, it was not possible to verify the precise type and stage of a claim, nor was it possible to check the reported fluctuations in a family's income during each subject's recuperation by alternative means. Hence, the following information was cross-checked, by indirect questioning, at the time of interview.

Few subjects (15%) reported that they were covered by a personal insurance policy at the time of their accident. Four (4%) people stated that they had benefitted from a permenent health policy, while 11 (11%) subjects had been covered by a personal accident policy. However, the vast majority of people questioned (84%) had no personal insurance cover at all.

Of the group as a whole, 29 (28%) subjects said they were pursuing a personal injury claim; 18 (62%) of which were motor claims, 8 (28%) were employer's liability claims and 3 (10%) were claims that were being handled by the Motor Insurance Bureau. The majority (86%) of claimants had lodged a claim by their 38th week post-injury, but 3 (10%) people were in consultation with their solicitor still and one (3%) person was unsure whether or not his claim had been lodged. Where a claim was known to have been lodged by the week of the final interview, 14 (48%) claimants had undergone at least one medical examination and 2 (7%) claimants knew that a writ had been issued on their behalf, even though they had not undergone a medical examination.

With respect to subjects' home finances during their recovery, 100 subjects were asked about the state of their income during this period and whether their household income had increased, had been maintained, or had decreased as a result of their injury. About half (51%) the group stated that there had been no difference in their financial circumstances during their recovery. Just under half (47%) the group reported that, overall, their income had decreased during their period of incapacity, while 2 (2%) subjects confirmed that they had been better off as a consequence of their injury. One of these two subjects was a 17 year old football player who was injured in a fight which had broken out on the football field. He had been kicked in the ribs and leg, but despite benefitting from a personal accident policy, he had returned to his job, as a car valet, 10 weeks post-injury. Nevertheless, during his 10 weeks sickness absence he had been in receipt of a larger income. The second subject was a 29 year old, unemployed miner who had fractured his leg with a chain saw whilst cutting logs at his home. This young man was married with four children and, although he was not covered by insurance, he stated that his sickness benefit had been in excess of the income which the family usually received.

5.6. Summary and Conclusions

This chapter set out to describe the type of patients included in this stu y in terms of the physiological, socio-economic, psychological and functional variables outlined in Chapter 3.4. in order:

- to provide background information for the statistical analyses contained in the subsequent chapter (see Chapter 6)
- to provide comparative data for future studies in this area of enquiry
- to enable the design of future experimental research to take account of the incidence of certain important characteristics of patients with diaphyseal fractures of the tibia and femur.

As anticipated, the series comprised mainly young, active, male football players and motorcyclists, the majority of whom were single and under 30 years of age. A substantial number of these individuals where still living at home with their parents and were employed in manual jobs at the time of their injury.

Typically, the type of injury sustained by subjects was a simple fracture, of the lower third of the bone, which was either transverse, oblique or spiral and minimally displaced and angulated. Many of the lower leg injuries were accompanied by a fibular fracture at the same level as the tibial fracture, but, otherwise, subjects had sustained few associated or secondary injuries of lesser importance to their tibial or femoral fracture.

Initially, the favoured method for treating tibial fractures was conservative management in a POP cast, while femoral fractures tended to be treated by methods of primary internal fixation. Nevertheless, half the group underwent two or more procedures, a third of which were carried out during the first week following injury - although at least one procedure was conducted during the subject's 41st week following injury.

During their recovery, subjects were found to be at most risk from infection (14%) or displacement of the bony fragments (14%). However, despite the diagnosis of a number of cases of "delayed" or "non-union", all the fractures went on to unite.

The median time at which subjects were instructed to start partially weight bearing, on their fractured leg, was 4.5 weeks following injury and, where known, the median time recorded for the fractures to unite was 26 weeks. In other words, although the intervals at which the clinical data were recorded were arbitrary and of dubious sensitivity, only 50% of the fractures were confirmed to have united by their 26th week following injury. Clearly, this finding casts doubt upon the appropriateness of using a criterion of 16 weeks, or even 20 weeks, as a "normative" standard against which to assess fracture healing, since, according to these standards, the majority of fractures in this series would have been categorised as "delayed" and so potential candidates for interventory treatment. In effect, it is more likely that this standard was unrealistic and this point is considered in greater detail in Chapter 7.

Data derived from two home interviews, scheduled to fall in each subjects' 16th and 38th week following injury, were used to describe comparable stages of recovery for the series as a whole. It is argued that much of this descriptive information confirmed suspicions that a time scale of 16 weeks, for recovery following lower limb fracture, was inappropriately optimistic for a substantial number of people included in this series. For example, despite the fact that treatments were not standardised for this population of patients, a third of all subjects still had their fracture externally immobilised at this point in time; a fifth of the group were dependent upon walking aids and approximately half the group reported that they experienced pain, at least sometimes, when they were weight bearing on their injured leg.

In keeping with these findings, just one third of working people were back at work 16 weeks following injury. Although subjects seemed to have been deterred little in terms of the frequency with which they got out and about, a considerable percentage of motorcyclists, car drivers and sports people reported that they had not resumed their former driving and sporting activities by this stage in their recovery..

An attempt was made to establish the general difficulties experienced by subjects in terms of specific functional abilities required by them in order to perform their former job or pastime activities. As a result of this exercise, it was not surprising to discover that the main problems, reported by subjects, were associated with running and jumping. A less expected discovery was that kneeling, climbing ladders and maintaining awkward postures were considered to be difficult or impossible to perform by a large number of subjects at the time of their first home interview. In fact, fewer than half those people who said they needed to run, jump or kneel said they could do so, without difficulty, 38 weeks following injury. However, the persistence of these functional limitations did not appear to coincide with the incidence of clinical signs, such as reduced limb bulk or restricted knee and ankle ranges of movement and there was a suggestion that health attitudes might have been influenced by subjects' experiences during recuperation (based upon the finding that such attitudes changed over time - see Chapter 4.2), although no firm conclusions could be drawn from these observations.

Thus, the next stage of analysis was to establish the potential effect of various independent variables upon a select number of outcome measures in order to identify factors which might need to be taken into consideration when planning future experimental, clinical trials.

Several clinical variables which might need to be controlled have been identified already in connection with existing attempts to classify fractures (see Chapter 1.3). However, hitherto, many of these classifications had arisen as a result of intuition rather than from systematic enquiry and, frequently, such typologies had been based upon multivariate grading systems which have served to confound the affect of a single, independent variable upon outcome. Therefore, it was decided to examine the relationship of independent variables upon one example each of physiological, socio-economic, psychological and functional outcome using non-parametric measures of correlation. As a result of these univariate analyses, the combined affect of those independent variables which were found to be significantly associated with time to union and return to work were explored further using a multivariate statistical procedure known as survival analysis. A brief description of the statistical techniques and the results of these analyses are presented in the next chapter, Chapter 6.

CHAPTER 6

FORECASTING RECOVERY FOLLOWING FRACTURE

6.1. Introduction

The third and final aim of this research project (see Chapter 3.1) was to perform *post hoc* analyses on the data so that potentially important prognostic indicators (such as severity of injury or site of fracture) could be examined in relation to the various outcome measures employed to monitor recovery in this study. However, only variables which were known to have produced accurate and consistent information were included in the analysis and the majority of variables used for this purpose were based upon factors believed to affect outcome. For this reason, many of the associations discussed during the course of the chapter will be familiar to experienced clinicians, but it must be stressed that, to date, surgeons have not reached a concensus of opinion as to which factors actually affect healing. For example, while Ellis (1958a) considered fracture site to be unimportant, Nicoll (1964) categorically stated that fracture site was important. Which expert is to be believed? Hence, there were two main purposes for using the statistical procedures discussed here. One reason was to investigate the controversy surrounding this issue in order to establish whether the methods of science could substantiate any of the conflicting views expressed so far (see Chapter 1.3). While the other reason was to demonstrate the kind of research design that would be required to subject such views to more thorough empirical evaluation.

The statistical analyses were conducted in two stages. Firstly, variables associated with four of the predetermined outcome measures were identified using non-parametric correlation techniques. This initial stage of evaluation was used to select, from the many plausible relationships, only those variables which were found to be statistically related to the different end results attained by subjects included in this series. During the course of this exercise, a note was made of those associations which appeared to validate certain popular clinical beliefs and those which did not - although, as will be shown, such substantive outcomes should be regarded with appropriate caution. Secondly, having identified factors related to the four different outcomes, six items were chosen from the two groups of variables associated with time to union and time to return to work in order to form the basis of two separate survival analyses. This second stage of evaluation aimed to identify the relative importance of the six variables included in each model for predicting time to union and time to return to work, respectively. Examples of the application of this procedure for hypothesis testing have been included at this point and, together, these two techniques have been used to exemplify the way in which objective statistical procedures may be employed to test the relevance of cherished beliefs inspired through the methods of authority, intuition and rationale (see Chapter 2).

As stated in Chapter 4.4, at the outset of the project, there was no agreed method for measuring recovery following lower limb fracture and no way of knowing which of the measurement instruments included in this study would produce sufficiently consistent data to be used in this way. Therefore, the measures of association presented in the first part of the chapter and the survival analyses discussed in the latter part of the chapter, necessarily were performed following knowledge of the results outlined in the preceding two chapters and, as such, were conducted as *post hoc* or *a posteriori* statistical analyses(9). In other words, although one of the original objectives of the study was to examine the data for possible statistical relationships between variables, it was not feasible to specify in advance hypotheses which could be tested at this stage because it was impossible to predict which (or, indeed, if any) of the variables would produce reliable data. Thus, whilst *post hoc* comparison offered a legitimate means for examining descriptive data, it must be emphasized that this method of analysis may have increased the likelihood of identifying spurious associations between variables and, hence, the main purpose of the exercise was to highlight relationships which could be tested prospectively.

For this reason, the task was undertaken, not by correlating every variable with every other variable in a haphazard attempt to "dredge" (Hampton, 1987) the data of all possible paired associations, but by undertaking a systematic analysis of each variable (which had produced at least ordinal level data) with one example of physiological, socio-economic, psychological and functional outcome. Then, to complete the analysis, the combined effect of certain variables, found to be significantly associated with time to union and return to work, were examined in greater detail using a statistical procedure known as survival analysis.

The reasons for opting to use these two particular statistical procedures were twofold:

- firstly, the correlation analyses were intended to identify factors that may have influenced outcome following lower limb fracture and, therefore, offered the opportunity for these to be taken into account in the design of subsequent experimental trials (if not held constant, the influence of such variables might be to confound the effects of any experimental condition under scrutiny.)
- secondly, the survival analyses were intended to demonstrate the relative importance of certain variables, found to be significantly associated with time to union and time to return to work, and, by doing so, to offer a model for the future analysis of other data relating to other populations of patient.

These statistical techniques are described, and the results of the analyses presented, in the next two sections of this chapter.

6.2. Univariate Analysis using Non-parametric Correlation

In Chapter 4, correlation techniques were used to establish the consistency of data over time and between raters in relation to an absolute criterion of 0.70. This application of correlation demonstrated one important use of the technique for establishing the reliability of instruments. However, correlation also is concerned with discovering whether a relationship exists between two, different variables and, in this context, it is used to determine the magnitude and direction of a relationship. So, although the technique could not be used to assign causality to variables, showing that a correlation existed between certain variables was a first step towards demonstrating a causal relationship.

Spearman's rank order correlation co-efficient, rho (r_s), was used to compute statistics for each pair of variables included in the analysis because the majority of the correlations were conducted upon ordinal data and, therefore, had to be analysed using non-parametric techniques. In this instance, it was appropriate to calculate the statistical significance of each co-efficient because it was possible that such relationships could have happened by chance. Therefore, a result was not deemed **statistically significant** unless its probability of occurrence by chance was 5 in 100 or less (ie $p \leqslant 0.05$).

The correlation analyses were conducted in two stages. Firstly, four dependent variables were selected (see next sub-section) and correlated with the remaining variables based upon ordinal or more precise scaling. (For the purpose of this task, a number of the binomial variables, eg sex, were included.) This resulted in the identification of four groups of variables, each member of which correlated significantly with one of the chosen dependent variables. The second stage of analysis entailed inter-correlating members of each of the four groups to ascertain which variables were the most strongly inter-related and, therefore, which separate items were the most likely to have influenced outcome.

6.2.1. Selection of dependent variables

Initially, seven dependent variables were selected as potential measures of outcome; three of which were clinical measures (ie time to union, complication rates and incidence of malunion), while four were rehabilitative measures (ie range of joint movement, return to work, resumption of activity and functional ability). However, with the exception of time to union and return to work, each of these measures comprised several items. For example, malunion was considered in relation to valgus, varus and fragment overlap and functional ability was considered in relation to ten different functional requirements usually performed by subjects during the course of their working day or pastime activities (eg kneeling or running).

In addition to the seven clinical and rehabilitative variables noted above (and as a consequence of verifying and testing the reliability of all the data), it was suggested that Questionnaire Two, the Health Locus of Control, might also be treated as a measure of outcome (see Chapter 4.2). This suggestion was made because it was found that, despite alternative evidence establishing the reliability of the HLC scale, attitudes held by subjects recruited to this study were susceptible to change and so may have been influenced by other variables. Thus, a total of eight instruments were considered as potential measures of outcome following lower limb fracture and, of these, four were chosen to determine which of the remaining variables were associated with recovery. The four variables selected for this purpose were: time to union, return to work, the total HLC scale and the ability to kneel.

Time to union was included as an indicator of physiological recovery because it was considered of clinical importance to do so. Despite reservations about the properties of measurement of this instrument (see Chapter 2.3), time to union was the most widely used measure for the clinical assessment of fracture healing and, as such, required attention. Furthermore, of the three clinical measures, this variable offered the highest level of quantification (see Chapter 2.2) and provided the highest intra-rater reliability co-efficient (see Chapter 4.3).

Similarly, time to return to work was selected as a measure of socio-economic outcome because it was acknowledged as an important stage of recovery for working people - even though it only applied to a sub-group of subjects and was associated with the type of work performed by employees. As with time to union, this measure also provided data of the highest level of quantification (see Chapter 2.2) and, although the intra-rater reliability of the measure was not calculated, data obtained for this variable correlated very strongly with equivalent data collected 16 and 38 weeks following injury (see Chapter 4.3).

The total score for the HLC scale was used as a third dependent variable to indicate psychological outcome. As described earlier (see Chapter 5.5), subjects' total HLC scores were split into low or high scores denoting subjects with a relatively internal versus external orientation, respectively. The total HLC scale was used in preference to either I-E scale because this was the only one for which adequate reliability data was available (Wallston et al, 1976).

Finally, the ability to kneel was used as an example of functional outcome because, during the course of the interviews, it was noted that subjects reporting difficulty with this particular function had undergone a specific method of fixation and, therefore, the ability to kneel was considered to have potential importance for the evaluation of various treatment methods. In fact, difficulty with kneeling was reported as the third most problematic function experience by subjects 38 weeks following injury and, while it would have been preferable to include all ten functional items as dependent variables, this would have biased the discussion. Therefore, the ability to kneel was used as an indicator of functional recovery because data for this variable correlated well with all the other functional data.

No attempt was made to use complication rates, the incidence of malunion, joint range or frequency of activity as measures of outcome. In the case of the first two and the fourth variable, the incidence rates for items included under these headings were considered to be too small to warrant further consideration as measures. While, in the case of the joint range data, the measurement errors associated with these recordings were considered to be too great to provide sufficiently sensitive instruments to measure change (see Chapter 4.3). This being so, these data have been included in the analyses as possible intervening variables.

6.2.2. Correlations with time to union

Time to union (recorded in weeks) was obtained for 81 subjects as described in Chapter 5.4. However, to permit analysis of the data using Spearman's rho, these results were converted into a simple ordinal scale to create three grades of outcome with approximately one third of subjects in each group. (The categories adopted were 0 to 20 weeks, 21 to 31 weeks and 32 weeks and over.) These data were then correlated with the remaining 82 variables which satisfied the reliability criterion set for this study (0.70) and which could be treated as ordinal level data. The findings of this exercise have been tabled, in full, in Appendix III.VII and resulted in 22 variables being significantly associated with time to union. These 22 variables and the statistics relating to them appear in Table 66.

While many of these associations may seem obvious, the reader is reminded that equally "obvious" associations demonstrated no statistical relationship with time to union. Hence, as stated earlier, the importance of this stage of analysis was to discriminate between those views which could be scientifically validated and those which could not.

Table 66: Significant Relationships between Time to Union and Other Variables

Variable	N	rho	p
	Correlation Co-efficients		
Physiological			
Severity	81	0.21	0.033
Fibular fracture	70	0.34	0.002
Treatment/Management			
Treatment 1	81	0.34	0.001
Week cast removed	62	0.42	<0.001
Immobilisation of limb*	80	0.28	0.006
Week partial weight bearing	70	0.25	0.019
Pain on walking*	77	0.30	0.004
Pain affecting sleep*	77	0.20	0.043
Delay/non-union	81	0.29	0.005
Clinical infection	81	0.23	0.018
Psychological			
I-score*	81	-0.21	0.033
Functional Activity			
Visiting: friends/relations*	58	-0.24	0.033
pubs/clubs*	77	-0.22	0.027
Functional Movement			
Knee flexion*	72	0.25	0.016
Knee extension*	72	0.35	0.001
Awkward postures*	58	0.40	0.001
Stooping/crouching*	68	0.20	0.049
Extensive walking*	71	0.27	0.011
Slopes/gradients*	72	0.21	0.042
Crossing difficult ground*	74	0.20	0.045
Running*	54	0.40	0.001
Climbing: ladders*	38	0.48	0.001

* data collected 16 weeks following injury.

It may be seen from Table 66 that **only two** of the variables used to classify fractures and describe their "personality" were found to be significantly associated with time to union and these were severity of injury and, in cases of tibial fracture, the presence of a fibular fracture.

As might be expected, the relationship between severity and time to union was such that compound fractures were associated with longer times to union and *vice versa* . This would appear to support the views of Ellis (1958a), Nicoll (1964) and others (see Chapter 1.3) that compound fractures may take longer to unite. However, there is, as yet, no statistical evidence to suggest that this relationship is causal. Indeed, compounding may be associated with longer times to union, but because compound injuries may be subject to infection or the use of particular methods of fixation, it may be that one or any combination of these or other factors may account for the delay. Hence, whilst this finding was important, it must be remembered that none of the associations discussed in the first part of this chapter represent "cause and effect" relationships and so the results in this section should be interpreted with due caution.

This having been said, the second clinical variable significantly associated with time to union was the existence of a fibular fracture in conjunction with a tibial injury. This finding was contrary to expectation in that the presence of an intact fibula was related to **shorter** times to union. Although, in the past, certain authors have refuted claims that an intact fibula can influence tibial healing (eg Nicoll, 1964), hypothetically, the presence of an intact fibula has been linked with longer times to union due to the assumption that the fibula can separate the tibial fragments, thereby creating a wider gap for the callus to bridge. However, this hypothesis was not supported by the findings of this study and, although it may have been that an intervening variable was responsible for the above association, the direction of the relationship is clear.

Interestingly enough, no statistically significant association was found between time to union and site, initial displacement, pattern of fracture (including comminution), angulation or any of the many other factors often quoted as having a potential affect upon union (see Chapter 1.3). Of course, this finding does not mean that such relationships did not exist and, clearly, these hypotheses should be explored further before firmer conclusions can be drawn. Nevertheless, in the current series of subjects, these variables were found to correlate very poorly with time to union and the likelihood of these associations having occurred by chance was unacceptably high (ie $p > 0.05$).

Another variable which correlated significantly with time to union was the type of initial treatment undergone by subjects. While it must be borne in mind that treatments were prescribed and, thus, the treatment groups were likely to have comprised dissimilar patients, it is note-worthy that treatments involving minimal intervention (ie cast only and MUA and cast) tended to be associated with shorter times to union while those involving greater degrees of intervention (including traction) tended to be associated with longer times to union. However, doubts about the selection of treatment methods, the accuracy of the measurement instrument (time to union) and the scaling of the variable make it difficult to judge the value of this finding. Certainly, it is arguable whether the treatment scale was ordinal and so whether it should have been included in the correlation analysis. Furthermore, although there was no demonstrable difference in the time to union displayed by subjects with femoral versus tibial fractures, the two bones were systematically treated using different techniques and there may have been factors indirectly associated with either treatment which accounted for this result. Nonetheless, the fact that a significant association was discovered between time to union and initial treatment method posed important questions about the efficacy of treatment and these will be considered in greater detail in Chapter 7.

Six other variables relating to the clinical management of subjects were significantly associated with time to union and these were: time to removal of cast (in weeks); whether or not the injured limb was externally immobilised 16 weeks following injury; time to partially weight bear (as instructed and recorded by the clinician); pain experienced when walking 16 weeks after injury; pain affecting sleep 16 weeks after injury; and the diagnosis of delayed or non-union. The fact that these six variables were related to time to union probably was indicative of the validity of clinical judgements being made at the time.

For prognostic purposes, a more meaningful relationship was confirmed in terms of the incidence of clinical infection and time to union - cases of infection being associated with longer healing times. This relationship would seem to support the widespread view (eg Sakellarides et al, 1964; Batten et al, 1978) that infection may interfere with the healing process.

The only psychological variable which significantly correlated with time to union was the I-score of the Health Locus of Control - low scores being associated with longer times to union. In other words, as anticipated, the less internally orientated subjects appeared to be in their attitudes to health, the slower their apparent physiological recovery. This finding was in keeping with the work of Snow and Thurber (1983) who suggested that patients suffering from undiagnosed complaints were more likely to demonstrate attitudes which had a stronger fate component. Whether or not such attitudes were shaped by subjects' experience of illness or injury and their subsequent treatment or whether they influenced union has yet to be established.

Of the remaining 11 variables that were significantly associated with time to union, two were concerned with activities performed by subjects, two related to joint range measurements and seven were functional ability items. The two activity variables demonstrated that reductions in activity, 16 weeks following injury, were associated with a more protracted physiological recovery. Limitations of knee joint movement, measured 16 weeks after injury, correlated with longer overall times to union and increased difficulty with adopting awkward postures, stooping/crouching, walking extensively, ascending and descending slopes, negotiating difficult ground, running and climbing ladders were all linked with longer times to union. Although, logically this was not surprising, it was helpful to confirm that the way in which data had been collected for the majority of these functional variables was related to the physiological outcome. (It should be noted that the ability to kneel does not appear in the list because it was treated as a dependent variable.)

Having considered the clinical and statistical significance of each of the forementioned relationships, the next step was to inter-correlate these 22 variables to determine which ones were the most strongly inter-related and which were likely to have had the greatest impact (if any) upon time to union. Excluding such obvious associations as the week a cast was removed (taken from hospital notes) with whether or not subjects' fractures were externally immobilised 16 weeks post-injury, the strongest and most highly significant relationships ($p < 0.001$) were found between severity and initial treatment method; infection and initial treatment method; and between all the functional variables - particularly the ability to walk extensively and the ability to stoop/crouch, negotiate slopes and cross difficult ground. The fact that the remaining variables were relatively less inter-related was taken to signify that they were more likely to have had a direct association with time to union. On these grounds, six variables were selected to represent important clinical and rehabilitative factors of interest for the prediction of time to union; namely, severity of injury, fibular fracture, clinical infection, time to partially weight bear, I-scores and the ability to walk extensively. These six variables have been used as the basis for the first of the survival analyses discussed in the latter part of this chapter.

6.2.3. Correlations with time to return to work

As with time to union, this dependent variable was converted into a simple three-point scale with approximately one third of patients falling in each category. (The resultant intervals for the scale were 0 to 16 weeks, 17 to 22 weeks and 23 weeks and over.) The correlation analysis was based upon data for 64 of the 86 employees who had been in work at the time of their injury. Sixteen former employees were still on sickness benefit at the time of their final follow-up interview, a further five people had not returned to work, either because they had been given notice or because they had resigned, and one subject had resumed work but could not recall the date of his return.

The correlation analysis was conducted along the same lines as described in the previous sub-section, but using time to return to work as a measure of socio-economic outcome. The full results of this exercise appear in Appendix III.VII. A total of 19 of the original 82 variables correlated significantly with time to return to work and these have been summarised in Table 67. Once again, it must be remembered that the purpose of identifying correlations with time to return to work was to limit the debate based upon common-sense associations to only those items that could be shown to be related to this outcome.

It may be seen from Table 67, that the three clinical variables associated with return to work included severity of injury and the existence of a fibular fracture. The direction of each association was similar to that found for physiological outcome - ie that longer times to return to work were related to compound injuries and to the presence of a fibular fracture. However, in addition to these two factors, the degree of initial angulation of the bony fragments also correlated well with time to return to work. This may have been because compounding was more likely to have been accompanied by angulation (and displacement). Thus, the greater the initial angulation, the more severe the injury, but it is interesting that this relationship was not demonstrated in the case of time to union. However, of the three clinical variables, the strongest and the most significant relationship existed between severity and time to return to work.

Table 67: Significant Relationships between Time to Return to Work and Other Variables

Variable	Correlation Co-efficients N	rho	p
Physiological			
Severity	64	0.43	<0.001
Fibular fracture	53	0.41	0.001
Angulation	57	0.32	0.007
Treatment/Management			
Week cast removed	46	0.40	0.003
Immobilisation of limb*	64	0.34	0.003
Socio-economic			
Social class	64	0.27	0.015
Circumstances of injury	64	0.37	0.001
Contact with GP*	62	0.22	0.043
Income	61	-0.25	0.026
Psychological			
E-score*	64	0.27	0.017
Perceived intrin. job char.*	49	-0.25	0.040
Happiness*	48	-0.38	0.004
Functional Activity			
Football*	64	-0.22	0.043
Functional Movement			
Knee flexion*	57	0.41	0.001
Awkward postures*	49	0.40	0.002
Crossing difficult ground*	59	0.25	0.031
Running*	51	0.37	0.004
Jumping*	56	0.30	0.020
Climbing: ladders*	29	0.63	<0.001

* data collected 16 weeks following injury.

Another similarity between socio-economic and physiological outcome was that both correlated significantly with time to removal of cast and whether or not fractures were externally immobilised 16 weeks following injury. In the case of conservatively managed fractures, this would appear to suggest that subjects tended not to return to work until their cast had been removed. However, it has been noted already that time to return to work was not significantly associated with time to union and, therefore, it is possible that alternative methods of fixation might enable patients to return to work more quickly than conservative methods of treatment. To safeguard jobs and in view of the economic importance of a timely return to work as far as patients are concerned, it is suggested that this hypothesis should be tested prospectively.

The circumstances of injury were found to be related to how soon employees had resumed their work. Subjects who merely slipped or tripped were more likely to have returned to work sooner than subjects who were injured as the result of a collision with another person or object. One obvious explanation might have been that the latter injuries were the more severe ones, but this was not a positive, significant finding (rho = −0.10, $p > 0.05$) which could imply that the circumstances, themselves, were of importance.

Of particular interest was the fact that longer times to return to work were significantly associated with having had contact with a GP, although the tendancy was for people with the less severe fractures to have said that they had seen their GP (rho = −0.42, $p > 0.05$). However, this trend was not statistically significant. It is notable that time to return to work was not related to reported contact with any of the other rehabilitation professionals or work personnel.

As already mentioned (see Chapter 4.3), return to work was significantly associated with social class and, hence, the more physically demanding a subjects' job, the longer it had taken him or her to return to work. Not surprisingly, the longer people were off work, the more likely they were to have said that their income had decreased during the period they were off. Yet, conversely, despite popular myths about malingerers, increased income was found to be associated with earlier returns to work.

Of the psychological scales, only three were significantly related to return to work - the E-scale of the HLC scale, and two of the Work and Life Attitude Scales. Higher E-scores were found to correspond with longer periods off work. Whatever, the reason underlying this relationship, it was interesting to discover that the dimension of externality had correlated with socio-economic outcome while the dimension of internality had correlated with physiological outcome.

The two Work and Life Attitude Scales significantly correlated with time to return to work were the perceived intrinsic job characteristics scale and the happiness scale. Subjects who reported that their jobs were relatively less responsible, varied, lacking in promotional opportunities and restrictive were more likely to have returned to work later than employees who held their job in higher esteem. Similarly, subjects who reported that they were not too happy had returned to work later than those who said they were very happy. The direction of both these relationships was predictable, although it can not be deduced that either attitude actually resulted in longer periods off work.

Curiously, the only activity variable which significantly correlated with time to return to work was the frequency with which subjects reported playing football 16 weeks after injury. The less frequently subjects said they had played football, the longer their period off work. Although, a rational explanation for this result might have been that subjects able to play football were likely to have been fit enough to work, the fact that the relationship was statistically significant was unexpected given the small numbers involved. However, this association may have been due to the fact that the majority of workers were involved in manual work and the physical demands of the two activities may have been similar. For example, earlier return to work was significantly related to full knee flexion and the ability to adopt awkward postures, cross difficult ground, run, jump and climb ladders. With the exception of climbing ladders, football players would have to have been able to perform all these functions as well.

Finally, having identified 19 variables which were significantly associated with return to work, these items were inter-correlated as a group. The strongest and most significant relationships ($p < 0.01$) were found between reduced knee flexion and time to removal of cast, the ability to run and frequency of playing football and the ability to climb ladders and time to return to work. After considering the practical implication and statistical significance of each item, six clinical and rehabilitative variables were selected for inclusion in the second survival analysis described in the latter part of this chapter and these were: severity, fibular fracture, angulation, social class, E-scores and the ability to cross difficult ground.

6.2.4. Correlations with the total HLC scale

Scores for the total HLC scale were used as the third dependent variable to represent a measure of psychological outcome. Data collected 38 weeks following injury was used for this purpose and split into two equal groups, about the median score, to create a two-point ordinal scale (as advocated by

Wallston et al, 1976). Hence, the lower score values from 11 to 39 represented subjects who were relatively internally directed while the higher values from 40 to 66 represented subjects who were relatively externally directed. Once grouped in this way, this simple scale was correlated with the same 82 variables used in conjunction with the other three measures. Only five variables were significantly associated with this psychological measure (see Table 68).

Table 68: Significant Relationships between the Total HLC Scale and Other Variables

	Correlation Co-efficients		
Variable	N	rho	p
Physiological			
Site of injury	97	-0.18	0.039
Pattern of fracture	96	0.33	0.001
Psychological			
Higher order need strength	67	-0.30	0.008
Socio-economic			
Insurance claim	97	0.23	0.012
Functional Movement			
Stooping/crouching	87	0.32	0.001

The associations between site, pattern of injury and the ability to stoop/crouch with the total HLC score were assumed to be spurious relationships. However, the remaining two variables that were significantly related to health attitudes were more plausible. Subjects who responded that, when looking for a job, they were not so concerned to use their skills, achieve something personally, make their own decisions, learn new things, be challenged or extend their abilities were more likely to have held fatalistic views about their health than people who apparently took personal responsibility for their health. Hence, feelings of personal control over one's health and work appeared to be related. Therefore, it was interesting to discover that subjects who were involved in an insurance claim as a consequence of their accident were more likely to have expressed a lesser sense of control over their health. The pertinent question which sprung to mind was whether these fatalistic views had resulted from events following the processing of a claim or whether subjects with a more external orientation were more likely to have been involved in a claim in the first place? Given that subjects who expressed greater control over their health also tended to have shorter times to union and subjects with a less fatalistic view tended to return to work more quickly, this finding may have clinical importance for the management of patients involved in insurance claims.

There were no highly significant ($p < 0.001$) inter-relationships found between the five independent variables. Thus, because of the small number of variables associated with this measure, it was considered that perhaps the total HLC scale did not provide an appropriate measure of psychological outcome, and this point is considered later in the chapter (see Summary and Conclusions).

6.2.5. Correlations with the ability to kneel

Subjects' reported ability to kneel 38 weeks following injury was used as the final outcome measure to represent functional outcome. Each subject was asked whether he or she needed to kneel in order to perform his or her job or other pastime activities and, if so, whether he or she could do so. Some 61 subjects responded that they had to be able to kneel, of whom 30 reported that they were able to kneel, 15 reported that they could only do so with difficulty, while 16 reported that they could not kneel. These data formed the basis of the fourth correlation analysis based upon function, the results of which appear in Appendix III.VII.

From Table 69 it may be seen that, in all, 32 variables were found to be significantly associated with the ability to kneel 38 weeks after injury. Three of these were clinical variables, namely severity, site of injury and pattern of fracture. The direction of these associations was that an inability to kneel was related to compound injuries, fractures in the lower third of the bone and more complex/comminuted fractures and *vice versa* . Of these three variables, the only exceptional result occurred with respect to more distal fractures being associated with greater difficulty in kneeling. But, on reflection, the fact that distal fractures of the femur were sited above the knee, while distal fractures of the tibial were sited above the ankle meant that whilst this coding was sensible in terms of time to union (the more distal the site, the potentially slower healing), it was not appropriate for assessing the affect of site upon the ability to kneel. Accordingly, this finding was of no clinical significance.

Table 69: Significant Relationships between the Ability to Kneel and Other Variables

Variable	N	rho	p
	Correlation Co-efficients		
Physiological			
Severity	66	0.21	0.042
Site of injury	66	0.21	0.042
Pattern of fracture	65	0.29	0.010
Treatment/Management			
Days of treatment	65	0.21	0.045
Week cast removed	41	0.42	0.003
Immobilisation of limb*	66	0.28	0.010
Pain on walking*	66	0.20	0.050
Delayed/non-union	63	0.30	0.008
Socio-economic			
Sex	66	0.24	0.027
Age	66	0.26	0.018
Social class	66	0.21	0.045
Psychological			
Opinion of recovery*	66	-0.43	<0.001
E-score*	66	0.21	0.046
Work involvement*	44	-0.27	0.039
Intrinsic job motivation*	44	-0.25	0.052
Job satisfaction*	43	-0.44	0.001
Overall job satisfaction*	44	-0.25	0.053
Perceived intrinsic job char*	44	-0.44	0.001
Happiness*	43	-0.32	0.019
Functional Activity			
Passenger: motorbike*	66	-0.24	0.026
Driver: car*	66	-0.27	0.014
Functional Movements			
Knee flexion*	62	0.42	<0.001
Plantarflexion*	50	0.25	0.039
Awkward postures*	55	0.37	0.003
Stooping/crouching*	65	0.47	<0.001
Extensive walking*	62	0.52	<0.001
Slopes/gradients*	61	0.48	<0.001
Crossing difficult ground*	65	0.53	<0.001
Running*	52	0.58	<0.001
Jumping*	48	0.47	<0.001
Climbing: stairs*	66	0.29	0.009
ladders*	36	0.44	0.004

* data collected 16 weeks following injury

Several treatment and management variables correlated with the ability to kneel and these were: the number of days to initial fixation, whether fractures were externally immobilised 16 weeks after injury and, where appropriate, the week of removal of casts. As anticipated, the later the initial fixation was applied or the longer a limb was immobilised, the greater the difficulty subjects said they had when attempting to kneel 38 weeks following injury. Likewise, the existence of pain on walking 16 weeks following injury and a diagnosis of delayed/non-union during recovery were associated with increased difficulty with kneeling later on.

Of the social variables, gender, age and social class were related to subjects' ability to kneel 38 weeks following injury. Women, older subjects and manual workers all reported more difficulty with kneeling than men, younger subjects and more professional people. The possible reasons for these findings were unclear as the ability to kneel was considered only in relation to subjects who said they needed to kneel to perform their job or hobbies and so presumably they had been able to kneel prior to injury.

Eight psychological variables were associated with kneeling as an outcome measure. Subjects' satisfaction with their recovery expressed 16 weeks following injury seemed to reflect functional outcome 22 weeks later - the less satisfied subjects were, the less able they were to kneel later on. Equally, the more fatalistic subjects' views about health 16 weeks following injury, the more limited their ability to kneel at 38 weeks. These two results could be interpreted in terms of subjects' motivation to recover. Therefore, it was particularly interesting to note that the ability to kneel correlated with no less than six of the Work and Life Attitude Scales. In all cases, the less involved, motivated, satisfied or happy subjects said they were with their job or life 16 weeks after injury, the less functionally able they said they were 38 weeks following injury. This finding could be construed as one reason for referring patients for various forms of therapy, since a number of studies (eg Booker, 1985; Partridge, 1985) have demonstrated the psychological benefits which may accrue as the result of therapy. Thus, it may be that these effects are of greater importance than whether or not subjects have improved muscle strength or increased range of movement. For example, despite the fact that knee flexion and plantarflexion were significantly associated with the ability to kneel (reduced range equating with reduced ability), the degree to which each range had to be limited before this could be reported with confidence was in the order of at least 8° to 15°, respectively (see Chapter 4.3). It is likely that reductions of this magnitude would be evident without the need to measure joint range.

In fact, it is suggested that a more appropriate measure of outcome was provided by patients' reports of what they could and could not do. Certainly, the ability to kneel was found to be significantly and positively related to all nine functional variables and, because of the strength of these individual associations, it was decided to inter-correlate just the functional variables to determine the internal consistency of these items. The results of this exercise are presented in Figure 4 and demonstrate the considerable agreement reached between each paired response.

However, despite the internal reliability between the functional items, the strongest inter-correlations for variables significantly associated with the ability to kneel were revealed between: reduced knee flexion and severity, removal of cast and the diagnosis of delayed/non-union; high E-scores and whether fractures were externally immobilised 16 weeks following injury; satisfaction with work and the importance of intrinsic characteristics in one's own job; and the ability to stoop/crouch with the ability to negotiate slopes/gradients. In other words, as expected, treatments leading to the immobilisation of a fractured limb contributed to decrements in knee function which were reflected, not only in the ability to kneel, but also in a number of separate attitudes and functions. Therefore, there was every indication that functional outcome was an important end result following lower limb fracture and that functional measures should be included in future clinical trials.

6.3. Multivariate Analysis using Survival Functions

In the second part of this chapter, survival analyses have been used to demonstrate the **relative importance** of select variables shown to be statistically as well as clinically related with time to union and time to return to work. The purpose of this analysis was to provide a model for the evaluation of different treatment methods adopted by clinicians in an attempt to address some of the many opinions expressed in the vast literature on fracture treatment.

Survival analyses may be conducted upon data derived from the measurement of time to an event or occurrence of concern. As the name implies, these techniques originated from survival studies which took death as the terminal

Figure 4: Correlation Matrix for Functional Variables

	Awkward Postures	Kneeling	Stooping	Walking	Slopes/ grad.	Dif. ground	Running	Jumping	Stairs
Kneeling	0.37**								
Stoop/crouch	0.52***	0.47***							
Walking	0.47***	0.52***	0.41***						
Slopes/grad.	0.30**	0.48***	0.40***	0.52***					
Dif. ground	0.40***	0.53***	0.47***	0.51***	0.40***				
Running	0.36**	0.58***	0.24*	0.49***	0.35**	0.50***			
Jumping	0.27*	0.47***	0.22*	0.40***	0.31**	0.33**	0.61***		
Stairs	-0.02	0.29**	0.19*	0.31**	0.38***	0.17*	0.34**	0.19	
Ladders	0.67***	0.43**	0.28*	0.36**	0.44**	0.23*	0.46**	0.22	0.28*

N varies from 36 to 99

* p <0.05
** p <0.01
*** p <0.001

event of interest and, in the past, typical applications have included drug and operative trials for the treatment of disease or malignancy and studies monitoring occupational mortality. Yet, these are by no means the only situations which lend themselves to the use of the techniques and many types of study, with a time-to-response outcome, may be treated in the same way. In fact, over the past twenty years, there has been an increased number of studies of this kind which has prompted the further development of statistical tests to analyse time-based data (Armitage & Berry, 1987).

There are two main features which distinguish the use of survival analyses from other statistical procedures. Firstly, these methods are able to cope with individuals for whom the outcome has not occurred by the time of analysis. Data of this kind are referred to as censored values and the benefit of including incomplete or censored observations in an analysis is that patients lost to follow-up, are not lost to analysis. (Unequal intervals between follow-up data pose no problem either.) Secondly, these tests can take into account the influence of prognostic factors upon outcome and, therefore, can distinguish between an experimental effect and the effect of other factors such as severity or infection. Clearly, under clinical conditions, where other factors cannot be held equal, this is of considerable advantage. (See Benedetti et al, 1985; Hopkins, 1985; or Armitage & Berry, 1987, for a more detailed account of these statistical techniques.)

In the current context, the two time-based events of interest were time to union and time to return to work. Both variables were used in the knowledge that neither was an ideal instrument of measurement and, yet, both had satisfied the fairly stringent criteria set for this study.

6.3.1. Forecasting time to union

As a result of correlating 82 variables with time to union, 22 items were found to have a statistically significant association with this outcome and, of these, six were considered to have sufficient clinical or rehabilitative significance to merit further attention. Therefore, by a process of elimination, six variables were included in the first survival analysis and these were: severity, fibular fracture, clinical infection, time to partially weight bear, I-scores and the ability to walk extensively by 16 weeks following injury.

Because the first two variables in this list were common to both physiological and socio-economic outcome, these two items were used to demonstrate the application of the technique for hypothesis testing. Thus, although in the context of a descriptive study it was not appropriate to test hypotheses formulated after the data had been gathered, this has been done in order to exemplify the application of the technique and to raise a number of questions which may then be tested prospectively. (In the case of an experimental trial, the treatment conditions could be substituted for severity or fibular fracture in the following examples.)

Two null hypotheses were tested at this stage, namely:

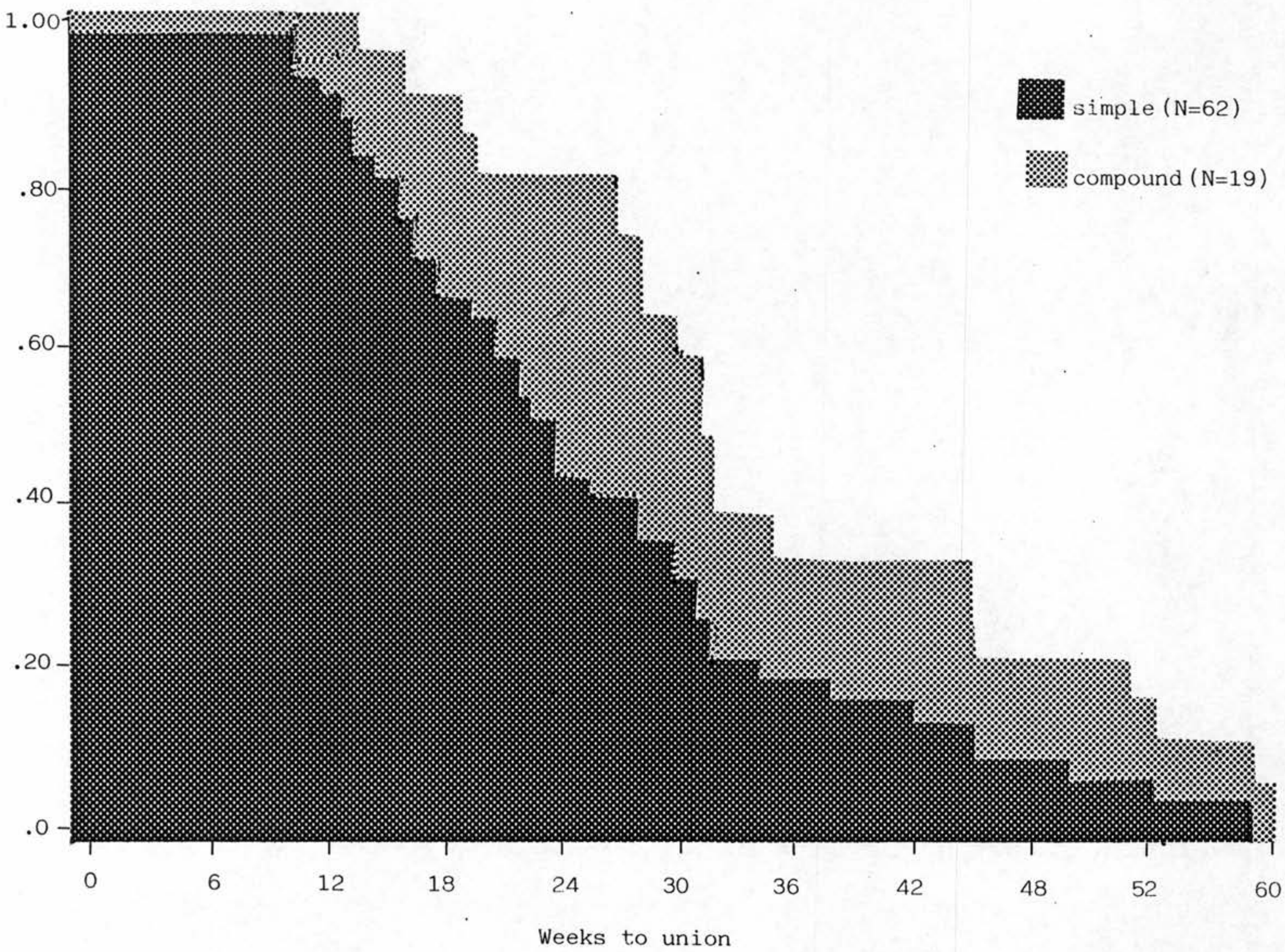
- that there was no difference in time to union between simple and compound fractures of the tibia and femur
- that there was no difference in time to union for tibial fractures which presented with or without a fibular fracture

The generalized Wilcoxon test, as proposed by Breslow, was used to test these hypotheses using the P1L programme (BMDP, 1985). This programme was used to compare the time to union distributions for the different sub-groups of subjects. The Breslow test was used, in the knowledge that it gave greater weight to earlier observations, because it was felt that reports of union were probably biased towards over-estimation of the time taken for union.

After conducting the above test, the null hypothesis for severity was rejected (Generalized Wilcoxon (Breslow) 5.51, 1df, $p = 0.019$) and, in fact, the mean time for simple fractures to have united was found to be significantly less ($\bar{x} = 25.87$ weeks, SE = 1.56) than that for compound fractures ($\bar{x} = 34.63$ weeks, SE = 3.24). Unfortunately, no conclusion could be drawn from this finding because the fractures had been treated discriminately. However, in the context of an experimental trial, or normative study, this observation would be of considerable importance.

Figure 5 diagrammatically represents the cumulative proportion of fractures reported as having united for the two categories of severity. The dark shading signifies the time to union taken by simple fractures while the lighter shading represents the additional time to union taken by compound fractures. The

Figure 5: Cumulative Proportion of Simple/Compound Fractures Uniting



convergence of the shaded areas towards the far right-hand end of the horizontal axis represents the point at which all the fractures were said to have united.

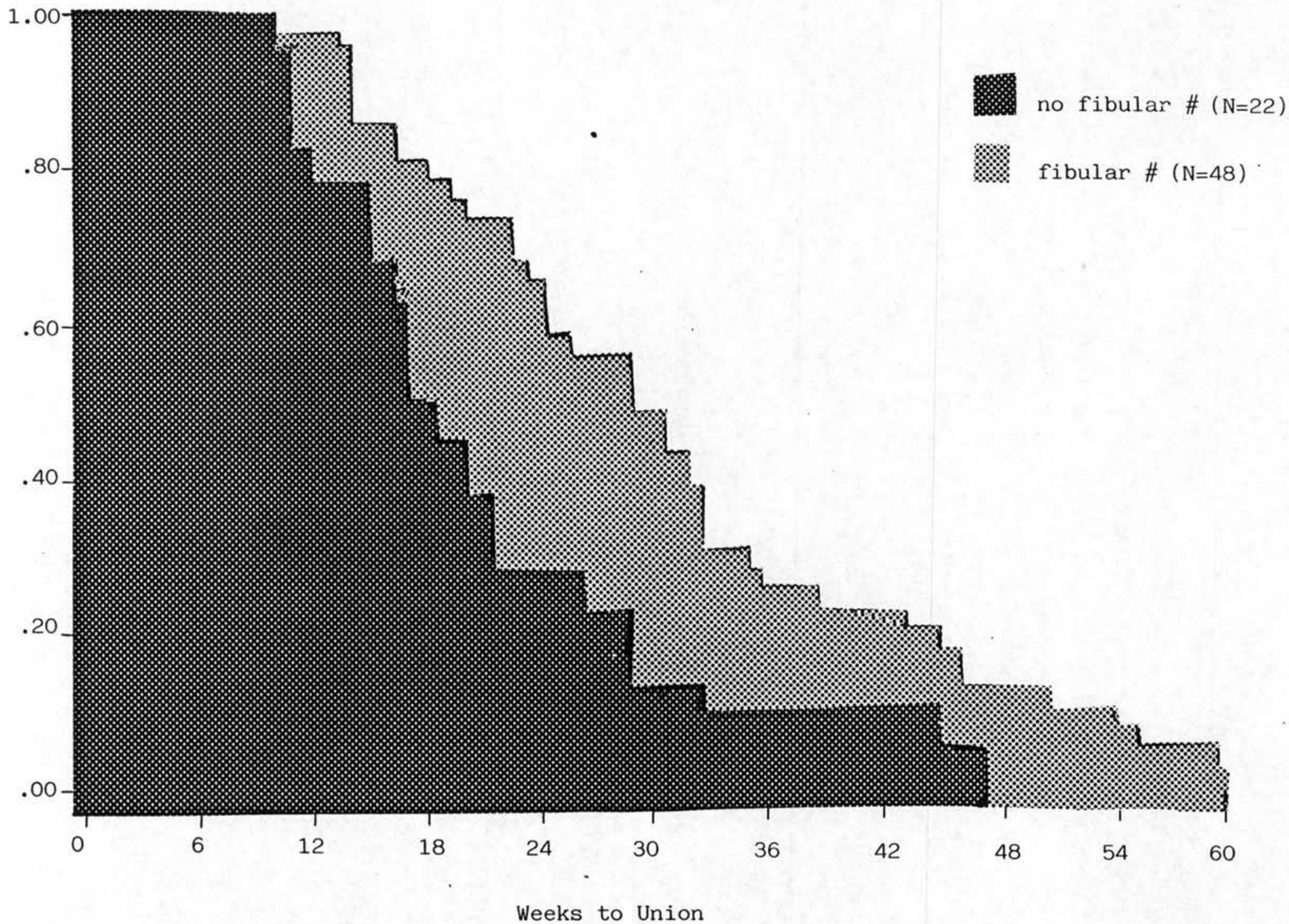
The next figure, Figure 6, gives a similar output for the time to union of tibial fractures presenting with or without a fibular fracture. As stated earlier in this chapter, an intact fibula was associated with earlier times to union and this is clearly shown by the darker area in the figure. However, the important question was whether this difference was statistically significant. As above, the null hypothesis was rejected (Generalised Wilcoxon (Breslow) 9.98, 1df, $p = 0.002$). Where the fibula was intact, tibial fractures had taken an average of 20.73 weeks (SE = 2.11) to unite and this was significantly less than the time taken to achieve union in cases of fibular fracture ($\overline{x} = 29.79$ weeks, SE = 1.91).

The two examples cited above demonstrate one means of testing *a priori* hypotheses in other studies. Since it was not possible to specify hypotheses in advance of performing the correlation analyses (simply because the purpose of the study was directed towards identifying relationships in order to specify hypotheses which could be tested prospectively), it was futile to repeat this exercise for each of the six variables. Instead, the question was asked as to which of the six variables had contributed most to the end result - in this instance, time to union.

To answer this question, a stepwise regression analysis, based upon Cox's proportional hazards model (Hopkins, 1985), was used in order to quantify the relationships between outcome and the six potentially prognostic variables. These statistics were computed using the P2L programme of the BMDP statistical package (BMDP, 1985).

The technique presumed that outcome (ie rates of union) may be modelled as log-linear functions of a set of covariates. Regression co-efficients were then calculated which related the effect of each variable upon outcome. The stepwise selection of variables resulted in the entry or removal of each item on the strength of significant probabilities calculated from a large sample of partial likelihood ratio tests. In other words, on the basis of an initial set of calculations, the most promising member was entered into the model and the relevant statistics were recalculated. This process was reiterated until the

Figure 6: Cumulative Proportion of Tibial/Fibular Fractures Uniting



model exceeded the limits of significance set to enter (0.10) or remove (0.15) the remaining terms. In this way, a summary of stepwise results was computed which hierarchically listed those factors that best predicted outcome. The results of this stepwise analysis are presented in Tables 70 to 72 for time to union.

Table 70 gives the initial statistics used to enter or remove variables to or from the model. It should be noted that in order to perform this procedure, ordinal data had to be converted into binary data such that each scale point above the first was entered into the analysis separately. For example, the ability to walk extensively comprised a three-point scale and so appeared twice in the variable list - once signifying able/difficult and once signifying able/unable.

Table 70: Stepwise Regression Analysis for Time to Union - Step 1

Variable	Approx Chi-sq enter	Approx Chi-sq remove	p	Log Likelihood
Severity	2.00		0.1572	-207.03
Fibular fracture	2.50		0.1140	-206.78
Clinical infection	3.99		0.0459	-206.04
I-score	1.43		0.2313	-207.31
Week partial wt bearing	10.06		0.0015	-203.01
Extensive walking (able/diff)	0.07		0.7887	-207.99
Extensive walking (able/unable)	7.07		0.0078	-204.50

Step Number 1 Week partial wt bearing is entered

LOG LIKELIHOOD = -203.01
IMPROVEMENT CHI-SQ (2*(LN(MPLR)) = 10.06, 1 df, p = 0.0015
GLOBAL CHI-SQ = 7.47, 1 df, p = 0.0063

Variable	Coefficient	SE	Coeff./SE	Exp(coeff)
Week partial wt bearing	-0.0561	0.0213	-2.6304	0.9455

It is evident from Table 70 that the largest and most significant chi-square to enter a variable into the model was obtained for the time post-injury that subjects had been instructed to start partially weight bearing (as recorded in their hospital notes). Therefore, this variable was entered and the statistics recalculated for the other variables. The effect of removing this one variable from the calculations can be seen by comparing equivalent p-values in Tables 70 and 71. Following this second step, no variable was eligible for entry into the model (ie all the p-values were greater than 0.1000) and so the programme terminated.

Table 71: Stepwise Regression Analysis for Time to Union - Step 2

Variable	Approx Chi-sq enter	Approx Chi-sq remove	p	Log Likelihood
Severity	1.45		0.2278	-202.28
Fibular fracture	1.33		0.2493	-202.34
Clinical infection	1.78		0.1817	-202.11
I-score	1.82		0.1779	-202.10
Week partial wt bearing		10.06	0.0015	-208.03
Extensive walking (able/diff)	0.10		0.7460	-202.95
Extensive walking (able/unable)	2.36		0.1247	-201.83

No term passes the remove and enter limits (0.1500 0.1000)

The summary statistics for this stepwise analysis are given in the next table, Table 72.

Table 72: Summary of Stepwise Results for Time to Union

Step No	Variable entered	df	Variable removed	Log Likelihood	Improvement chi-sq	p	Global chi-sq	p
0				-208.03				
1	Wk PWB	1		-203.01	10.06	0.002	7.47	0.006

In conclusion, it would appear that of the six variables included in the stepwise analysis, the only predictor of time to union was the time at which subjects were **instructed** to partially weight bear (and not severity or infection as might be expected). As the median time for this instruction was 4.5 weeks following injury, it was unlikely that clinicians had given such advice on the basis of the stage of union demonstrated clinically or radiologically. This raised the question of whether early partial weight bearing is desirable - as suggested by Brown et al, 1969; Connolly et al,(1973); or Dehne, (1974) - or whether this finding was an artifact of clinical decision making? For example, the more wary the clinician about instructing a patient to weight bear, the more wary he or she may have been about declaring union. This aspect of patient management, though controversial, needs urgent attention because it is potentially one of the easiest and most economically viable ways of improving outcome for a substantial number of patients.

One negative point worth mentioning here, is the absence of clinical variables as predictors of time to union. Despite there being significant differences in time to union for subjects with simple and compound fractures and those with a fibular fracture or not, the actual timing of union could not be forecast very accurately by either. This concurs with the findings of other authors (eg Cornes, 1987; Partridge, 1985) who have suggested that more severe injuries are not necessarily indicative of less favourable outcomes. Interestingly, a behavioural factor would appear to be a better predictor of physiological outcome than clinical factors.

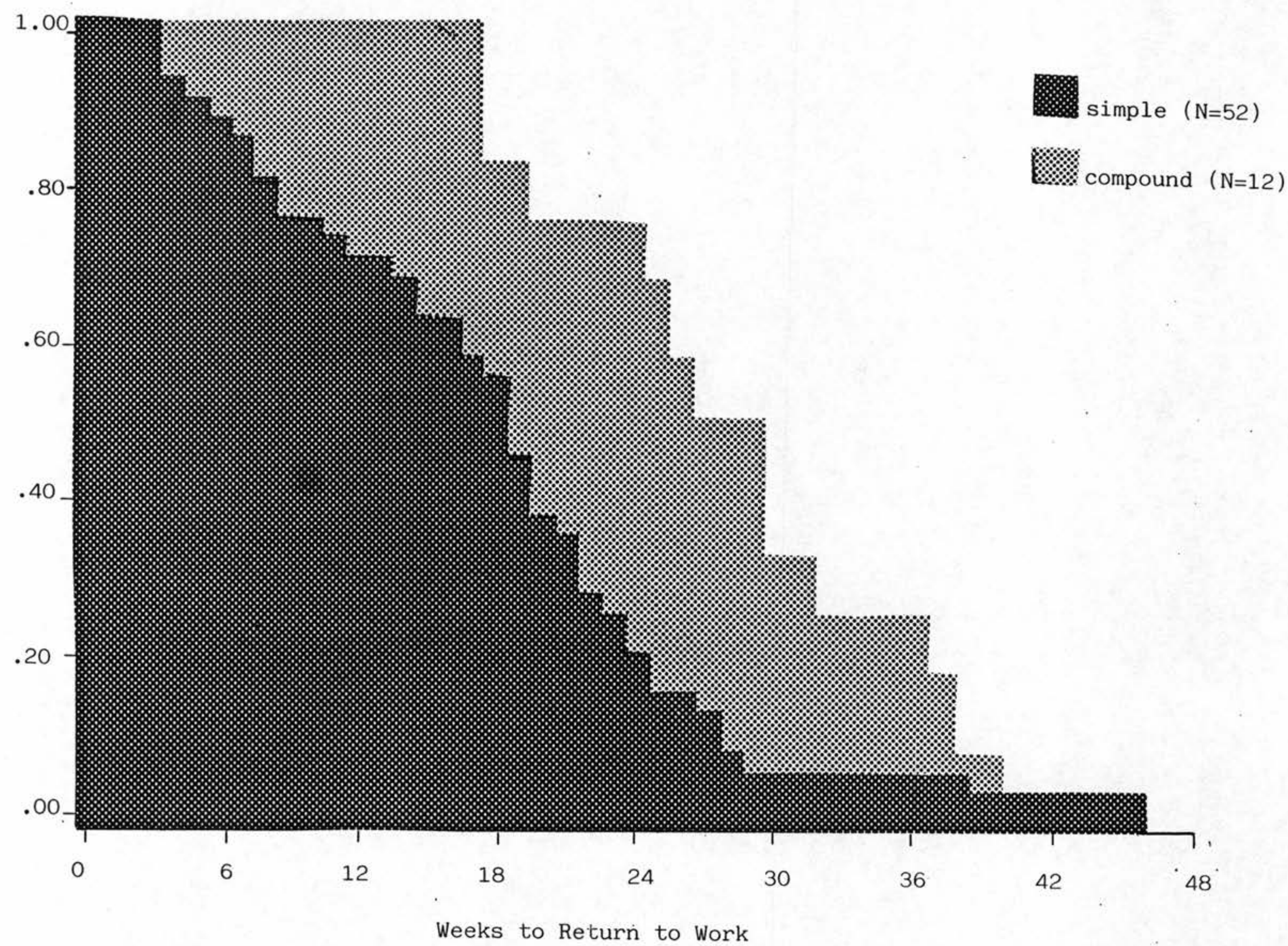
6.3.2. Forecasting time to return to work

By a process of elimination, six variables were identified for inclusion in the second survival analysis and these were: severity, fibular fracture, initial angulation, social class, E-scores and the ability to walk across difficult ground 16 weeks following injury. As with time to union, two hypotheses were tested at this stage in order to exemplify the use of survival analyses for the purpose of inference. The two null hypotheses were:

- that there was no difference in the time to return to work for subjects sustaining simple or compound fractures of the tibia or femur
- that there was no difference in the time to return to work for subjects with a tibial fracture presenting with or without a fibular fracture

Figures 7 and 8 diagrammatically portray the cumulative proportions of subjects returning to work for the two grades of severity and fibular involvement, respectively. In Figure 7, the darker shaded area represents the proportion of subjects with simple fractures who had returned to work at

Figure 7: Cumulative proportion of Subjects with Simple/Compound Fractures Returning to Work



varying intervals up to their 45th week following injury. The lighter shading denotes the equivalent proportion of subjects with compound fractures who had returned to work over the same period. Visually, there appeared to be a marked difference and, indeed, the null hypothesis for severity was rejected (Generalised Wilcoxon (Breslow) 9.47, 1 df, p = 0.002), the conclusion being that, overall, subjects with simple fractures had returned to work significantly sooner ($\bar{x}$ = 17 weeks, SE = 1.24) than subjects with compound fractures ($\bar{x}$ = 27 weeks, SE = 2.18).

Not surprisingly, the second null hypothesis also was rejected (Generalised Wilcoxon (Breslow) 8.81, 1df, p = 0.003). On average, subjects with tibial fractures without a fibular fracture had gone back to work significantly earlier ($\bar{x}$ = 14.24, SE = 1.74) than subjects with a fibular fracture ($\bar{x}$ = 22.08, SE = 1.67). This difference is shown in Figure 8. The darker shading represents the proportion of subjects with tibial fractures, without a fibular fracture, who had returned to work at any given time. The lighter shading represents the same for subjects with a fibular fracture.

This process was not repeated for the remaining four variables due to reasons outlined earlier.

Since it was already known that the six variables selected for inclusion in the second survival analysis were significantly related with time to return to work, the question posed was which of the six best explained the timing of return to work. Thus, the stepwise regression analysis was repeated for this data set using weeks to return to work as the time-dependent response. Ordinal data was converted into binary data as necessary and the results of this exercise are shown in Tables 73 to 76.

Figure 8: Cumulative Proportion of Subjects with Tibial/Fibular Fractures Returning to Work

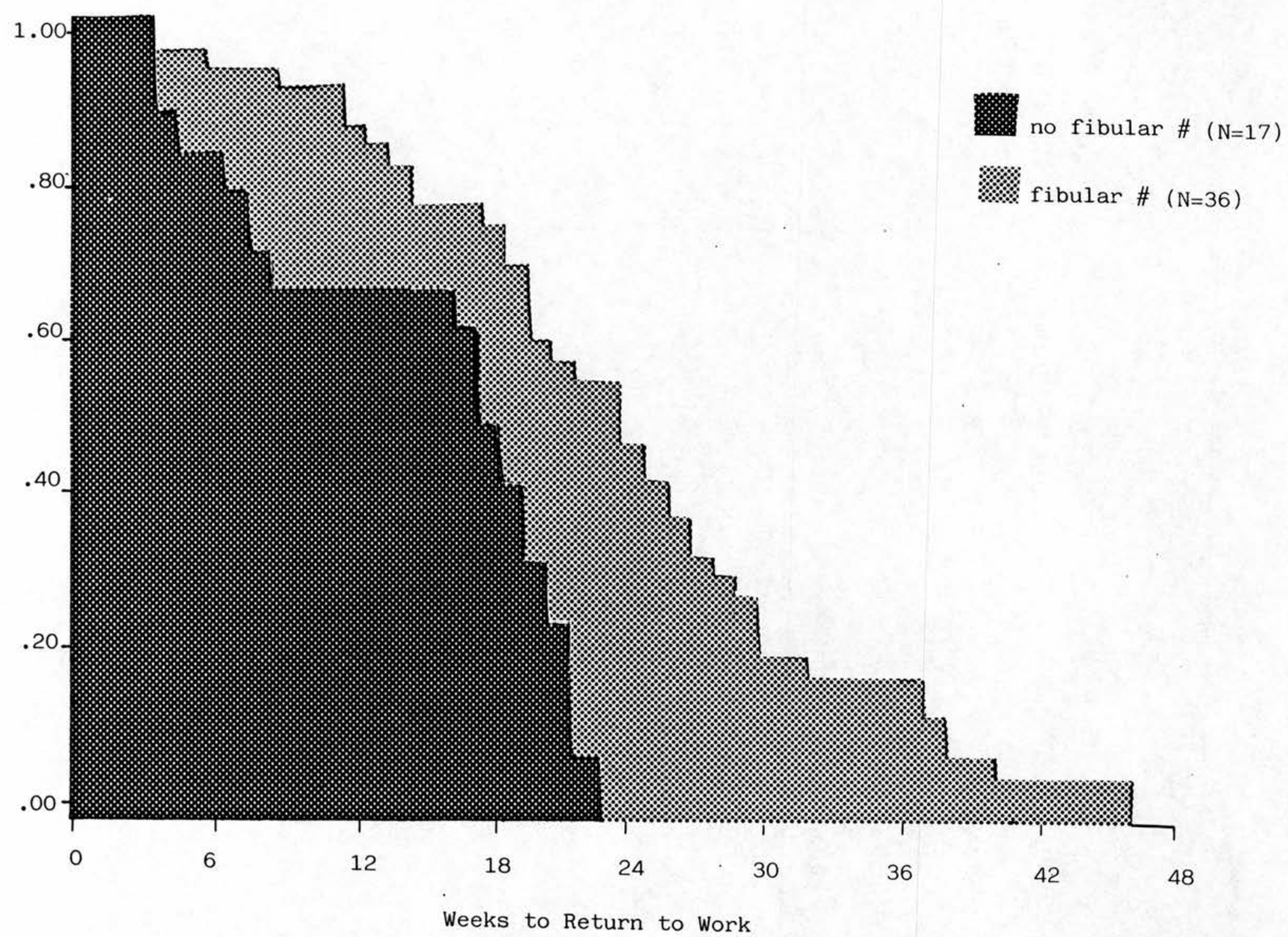


Table 73: Stepwise Regression Analysis for Time to Return to Work - Step 1

Variable	Approx Chi-sq enter	Approx Chi-sq remove	p	Log Likelihood
Severity	6.99		0.0082	-162.72
Fibular fracture	13.80		0.0002	-159.31
Angulation	4.10		0.0429	-164.16
Social class (1/2)	2.62		0.1052	-164.90
Social class (1/3)	0.90		0.3439	-165.76
Social class (1/4)	0.59		0.4428	-165.92
Social class (1/5)	0.35		0.5549	-166.04
Social class (1/6)	0.67		0.4147	-165.88
E-score	2.72		0.0991	-164.85
Crossing diff gnd (able/diff)	0.02		0.8993	-166.20
Crossing diff gnd (able/unable)	2.70		0.1001	-164.86

Step Number 1 fibular fracture is entered

LOG LIKELIHOOD = -159.31
IMPROVEMENT CHI-SQ (2*(LN(MPLR)) = 13.80, 1 df, p = 0.0002
GLOBAL CHI-SQ = 15.29, 1 df, p = 0.0001

Variable	Coefficient	SE	Coeff./SE	Exp(coeff)
Fibular fracture	-1.2159	0.3261	-3.7290	0.2964

It may be seen from Table 73 that the presence or absence of a fibular fracture seemed to have contributed most to the outcome of time to return to work and accordingly this was entered into the model first. Then the chi-square values were recalculated for the remaining variables and the next most significant contribution to outcome was shown to be severity. This too was entered into the model (see Table 74). Having entered a second variable, the chi-square values were adjusted once again and as none of the remaining variables satisfied the entry criterion of significant (ie p <0.1000), the programme terminated (see Table 75).

Table 74: Stepwise Regression Analysis for Time to Return to Work - Step 2

Variable	Approx Chi-sq enter	Approx Chi-sq remove	p	Log Likelihood
Severity	3.61		0.0575	-157.51
Fibular fracture		13.80	0.0002	-166.21
Angulation	0.52		0.4725	-159.05
Social class (1/2)	0.39		0.5333	-159.12
Social class (1/3)	0.02		0.8910	-159.30
Social class (1/4)	0.41		0.5214	-159.10
Social class (1/5)	2.41		0.1206	-158.10
Social class (1/6)	0.12		0.7275	-159.25
E-score	0.85		0.3558	-158.88
Crossing diff gnd (able/diff)	0.21		0.6475	-159.21
Crossing diff gnd (able/unable)	0.58		0.4481	-159.02

Step Number 2 severity is entered

LOG LIKELIHOOD = -157.51
IMPROVEMENT CHI-SQ (2*(LN(MPLR)) = 3.61, 1 df, p = 0.0575
GLOBAL CHI-SQ = 18.56, 2 df, p = 0.0001

Variable	Coefficient	SE	Coeff./SE	Exp(coeff)
Severity	-0.6407	0.3508	-1.8267	0.5269
Fibular fracture	-1.0600	0.3293	-3.2194	0.3465

Table 75: Stepwise Regression Analysis for Time to Return to Work - Step 3

Variable	Approx Chi-sq enter	Approx Chi-sq remove	p	Log Likelihood
Severity		3.61	0.0575	-159.31
Fibular fracture		10.42	0.0012	-162.72
Angulation	0.04		0.8441	-157.49
Social class (1/2)	0.16		0.6935	-157.43
Social class (1/3)	0.01		0.9185	-157.50
Social class (1/4)	0.62		0.4295	-157.19
Social class (1/5)	1.67		0.1960	-156.67
Social class (1/6)	0.09		0.7706	-157.46
E-score	0.39		0.5246	-157.31
Crossing diff gnd (able/diff)	1.11		0.2912	-156.95
Crossing diff gnd (able/unable)	0.16		0.6872	-157.43

No term passes the remove and enter limits (0.1500 0.1000)

A summary of the results of this second stepwise analysis is presented in Table 76. These results indicated that, in the case of tibial fracture, the best predictor of time to return to work might be the presence or absence of a fibular fracture, while the next best predictor might be severity of injury. This finding was contrary to expectation because other research (Cornes, 1987) had suggested that clinical variables were less promising predictors of return to work. In this study of personal injury claimants whose cases had been settled for £5,000 or more, it was suggested that age, sex, occupation, length of treatment, labour market conditions, spinal injury and psychological status had shown more promise as prognostic factors. However, these different findings were not necessarily contradictory, since it must be remembered that the lower limb fracture subjects formed a fairly homogeneous group comprising active, young men with a single major injury, who were performing mainly manual types of work and, in many cases, had not been involved in an insurance claim. Within such a group, it is more likely that the detail of injury would come to the fore rather than global factors appropriate to a more heterogeneous population of patients.

Table 76: Summary of Stepwise Results for Time to Return to Work

Step No	Variable entered	df	Variable removed	Log Likelihood	Improvement chi-sq	Improvement p	Global chi-sq	Global p
0				-166.21				
1	Fib	1		-159.31	13.80	0.000	15.29	0.000
2	Severity	2		-157.51	3.61	0.058	18.56	0.000

6.4. Summary and Conclusions

This chapter has described the process by which variables were further selected and tested as potential measures of outcome or indicators of recovery following lower limb fracture and this was undertaken in order to provide an illustrative example of how the methods of science could be applied in future clinical experimental research.

Four outcome measures were selected on the basis of their properties of measurement and wider usage to represent aspects of physiological, socio-economic, psychological and functional outcome. Eighty-two of the remaining variables were then correlated against these dependent variables and, as a consequence of this exercise, four groups of items were identified each member of which was significantly related to one of the particular outcomes. In this way attention was focussed upon a smaller number of factors which may have been causally related to each of the specific end results or which may help in forecasting outcome for future patients. For example, severity was noted as having been associated with time to union, time to return to work and the ability to kneel 38 weeks following injury and, therefore, it is strongly recommended that subjects entered into future experimental trials should be randoml y allocated to "treatment" groups using a stratified design to ensure that roughly equal numbers of subjects with simple and compound fractures are allocated to each group. This would ensure that the relatively smaller number of patients with compound injuries would be divided equally between the two groups rather than leaving this to chance.

Depending upon the number of subjects involved and the aims and complexity of the study, consideration should also be given to controlling for fibular fracture when using time to union or time to return to work as outcome measures for patients with a tibial injury. Likewise, when using the ability to kneel to evaluate the functional benefits of different treatments, it should be remembered that factors such as site of injury, pattern of fracture, sex, age, social class and work and health attitudes also may affect outcome.

During the course of this exercise a number of questions were raised about the nature of the relationships found between certain independent and dependent variables that may merit further investigation in studies specifically designed to test hypotheses addressing these questions. For example, questions were raised in connection with whether treatment, health attitudes and the time at which patients had been instructed to partially weight bear had determined recovery. It is suggested that these questions require urgent attention.

By a process of elimination, three of the original seven instruments were identified as being capable of measuring outcome following lower limb fracture and these were: time to union, time to return to work and the ability to kneel 38 weeks following injury. These three measures were shown to relate to 19 or more of the descriptive variables, while, by comparison, the chosen psychological measure performed relatively poorly, correlating with only five separate items. This would suggest that although the intra-rater reliability of the total HLC scale did not satisfy the requirements set out for this study, perhaps the health attitudes expressed by subjects were enduring after all and the scales more appropriately used as an intervening rather than a dependent variable. Accordingly, there are grounds for advocating the cautious use of time to union, time to return to work and the ability to kneel as outcome measures for this patient group. Equally, because of the high correlation found between the ability to kneel and the other nine functional variables which reached this stage of selection, it is suggested that any of the ten variables could be included as separate measures of function in order to cover an appropriate spectrum of functional abilities and because different patients will have different functional requirements. However, while subjects' attitudes towards health may have shaped or been shaped by their various experiences following lower limb fracture (and so there is reason to investigate the nature of these attitudes towards health in the future), there are no grounds for advocating the use of this particular scale as a measure of psychological outcome for this patient group.

Nevertheless, it must be stressed that in the hands of different operators these instruments could perform very differently and just because these measures have appeared to produce consistent data here, this property can not be assumed in the context of subsequent studies. In fact, as might be expected of subjective data, the inter-rater reliability for time to union was demonstrated to be very poor - $r = 0.29$ (see Chapter 4.3). The implication of this finding is that all measurements (but time to union in particular) should be standardised and the resultant data rigorously tested at the beginning of every study if any credibility is to be attributed to the event of interest. Once this has been achieved, these data could be used as one means to discriminate between the recovery made by different groups of subjects.

Finally, this chapter has described a novel means for statistically examining data relating to time to union and time to return to work for subjects who sustain a tibial or femoral fracture. Hitherto, arguments concerning which factors influence outcome and which procedures achieve the best results have frequently been addressed by comparing the descriptive results of single treatment groups, reported by different authors using different patients and different methods of assessment. This chapter has offered a model for using statistical techniques of correlation and survival analysis to test hypotheses in the context of one experimental trial or naturalistic study. Although both techniques have been widely employed (and survival analysis, in particular, has been used in medical research for the evaluation of drugs and operative intervention in cases of malignant tumour) the application of these techniques to analyse time-to-response data in the treatment of fracture offers a unique approach to the problem. It is suggested that this alternative method of analysis may be very suitable for analysing time-based data relating to both union and return to work in the context of an appropriately designed experimental trial. Therefore, while there remains the need to re-appraise critically the validity of instruments purporting to measure physiological and socio-economic outcome, and to improve the reliability and sensitivity of such measures, it is suggested that techniques of correlation and survival analysis could assist with the objective evaluation of both these types of data in order to substantiate or refute the numerous "opinionated and contentious views" (Ellis, 1964) expressed on the subject. These statistical procedures could be useful in clarifying which of the authoritative opinions are worthy of further consideration.

CHAPTER 7

GENERAL DISCUSSION, CONCLUSIONS, DEVELOPMENTS AND RECOMMENDATIONS

7.1. Overview of the Main Issues

This final chapter seeks to give coherence to the research described in the preceding chapters by summarising the main issues and conclusions arising from the study and discussing these within a broader framework. Therefore, although the preceding chapters describe the background, planning, execution and findings of a longitudinal study of 112 patients recovering following diaphyseal fracture of the tibia or femur, the main theme of the thesis is concerned with measurement and the scientific evaluation of treatment following lower limb fracture.

Originally, this study was initiated because of clinical concern over the length of time which a substantial minority of diaphyseal fractures of the tibia, in particular, seemed to have taken to unite; and a consequent desire to intervene early post-injury in an attempt to influence the healing process in such cases. Hence, there was a wish to predict those fractures which might require intervention and there was a need to evaluate the efficacy of various primary and secondary treatment solutions. However, during the course of reviewing the extensive literature on the subject of fracture treatment (see Chapter 1.2); the aetiology, incidence and character of such fractures (see Chapter 1.3); and the principles and practice of treatment (see Chapter 1.4) to plan such a trial; it became increasingly apparent that the controversy surrounding the subject had not been helped by the inadequate scientific rigour with which authors had tackled the problem of description, classification and experimentation. Part of this problem appeared to have arisen because of a lack of understanding about important aspects of the scientific method necessary in the social and behavioural sciences. Consequently, the focus of this study has been directed towards addressing the problem of how to measure outcome following lower limb fracture, and designing an appropriate methodology which could be used to test the success of treatment procedures in future clinical research.

7.1.1. Fracture treatment as a precise science

In the case of fracture treatment, the proposal to investigate the efficacy of different procedures, using the methods of science, emanated from the orthopaedic profession itself in response to widespread concern over certain complications associated with, and controversy surrounding, the treatment of diaphyseal fractures. Just over a decade ago, White (1975) presented an argument for using the methods of science to answer the question of how best to treat fractures and, more recently, a similar proposal has been made by Rudicel and Esdaile (1985) in relation to orthopaedic surgery in general.

To the credit of the speciality, concern about the treatment of this particular sub-group of patients has been registered in a wealth of literature on the topic and a considerable number of treatment interventions have been devised and directed towards minimising these difficulties (see Chapter 2.4). Yet, despite a vast literature on the subject of tibial fractures, especially, the majority of articles have persisted to ignore the call for objectivity and have continued to express views based upon invalid comparisons made between dissimilar series of patients. Thus, while there is no question about the appropriateness of the treatments described in each of these articles, authors' attempts to generalise about the wider application of such treatments is in question. Unfortunately, as discussed in Chapter 1.2, notable exceptions to this rule (eg Kenwright et al, 1986) have served to demonstrate a disregard for certain basic premises underpinning the scientific method and, to date, the problems associated with these injuries remain undefined and the challenge to investigate the benefit of treatment procedures remains uncontested. This would seem to suggest that, for various reasons, orthopaedic surgeons may be disinclined or ill-equipped to undertake the joint role of clinician and scientist (see sub-section - Professional conviction versus scientific uncertainty). Both jobs are demanding and can place unpredictable demands upon the surgeon or investigator. Both jobs require skilled knowledge, careful planning and meticulous attention to detail in their execution and follow-up. Hence, it is feasible that attempts to combine these two roles may have hampered the development of the treatment of fractures into a more precise science.

7.1.2. Description, Classification and Experimentation

The development of the scientific method in the social and behavioural sciences (and, thus, the clinic) advances through a sequence of stages entailing description, classification and, ultimately, experimentation - the experiment being central to the method of science. In clinical practice, the essence of the experiment is replicated in the randomised clinical trial which has been used extensively for the evaluation of new drugs prior to making these more generally available. However, in contrast with the laboratory experiment, the design of a clinical trial relies upon the investigator's knowledge of the clinical situation within which the experiment will be conducted. Unlike the laboratory, where the environment can be carefully controlled, the clinical environment cannot be held constant for all subjects and, hence, it is vital that the design of a clinical trial attempts to eliminate the effect which other variables might have upon the end result.

For this reason, it has been said that hypotheses which are worth testing in the social sciences can only be developed in areas about which a good deal is known - in other words, where a great deal of sound empirical data has been collected (Stacey, 1969). Certainly, before this stage of hypothesis testing most studies are of an exploratory nature because they seek to provide an accurate account of events in an attempt to identify questions worthy of attention. However, there is little advantage to be gained from having access to a considerable literature on a subject, if this literature is contradictory. In other words, in order to conduct relevant clinical research, it is essential that empirical descriptions are known to be precise and that they support a certain line of enquiry so that appropriate hypotheses may be formulated and assessed in a methodical manner.

Unfortunately, in the case of tibial and femoral fracture, the absence of a systematic approach to obtaining and documenting data has served to obscure rather than clarify the issues of importance for the design of a clinical trial. As stated earlier, much of the literature was found to be contradictory and apparently was based upon ill-defined, non-standardised judgements rather than measured empirical observations. Therefore, there were not only serious doubts about the accuracy of such data, but also considerable dispute over the potential impact that other factors might have upon outcome and disagreement over the way in which recovery was assessed. This was exemplified in the highly individualised ways in which authors have dealt with the problem of classification (see Chapter 1.3) and measurement (see Chapter 2.3). Because the design of an experimental trial has to take these factors into account, it was decided that there was a need to collect additional descriptive data and to improve the tools for measuring recovery. Therefore, instead of attempting to proceed with a clinical trial founded upon existing descriptions, classifications and *ad hoc* measures, and in view of the longstanding debate surrounding the topic, it was considered essential that progress should be made by creating a sound empirical basis from which to develop the treatment of fracture into a more precise science. To achieve this general objective, a longitudinal study of patients' recovery following diaphyseal fracture of the tibia or femur was planned with three specific aims in mind (see Chapter 3.1).

7.1.3. Measurement following fracture

The first of the three aims of this study was to select and test instruments capable of measuring physiological, socio-economic, psychological and functional outcome following lower limb fracture - for without accurate instrumentation it would prove impossible to demonstrate the effect of treatment objectively. Thus, prior to selecting appropriate measures for this purpose, the exact nature of the problem had to be defined (eg union taking x weeks or more, valgus deformities of 10° or more etc.) to enable appropriate measures to be chosen.

Not surprisingly, authors differed in their perceptions as to what constituted recovery and, therefore, what should be monitored and how. Certain authorities perceived the problem in physiological terms based upon time and referred to "average" times to union as a standard against which to assess the rate of bone healing. As a consequence, fractures taking longer than "average" to unite were labelled "delayed" (eg Nicoll,1964; Crawford-Adams, 1983). However, the way in which union was determined and the exact cut-off point denoting "acceptable" from "unacceptable" times to union were found to differ from study to study, primarily due to the fact that definitions were neither founded upon standard testing procedures nor population normative values.

Quite understandably, other authors viewed this yard-stick as arbitary and put forward suggestions to improve the basis on which times to union could be compared - for example, cumulative percentage data (Austin, 1978). Yet other authors considered "time" to be a meaningless point of reference and thought that the best test of success was the quality of end result and not the time taken in achieving that end result (Watson-Jones, 1953). Needless to say, "quality" was interpreted to mean different things by different authors including the absence of malunion or deformity and the ability to return to work or perform various activities or movements. Once again, data describing these end results tended to be derived by dubious means (see Chapter 2.3-2.4).

In conclusion, it was felt that little confidence could be placed upon the accuracy of existing instruments simply because there was no evidence to suggest that they had been applied in a precise way. This was not to imply that the instruments themselves were necessarily poor, but rather that they were inadequately explained and, therefore, their properties of measurement were unknown. Hence, the fact that there was no agreed way to measure outcome following fracture of the lower limb meant that appropriate measures had to be identified or devised and tested prior to their use in the context of a clinical trial. In response to this observation, considerable attention has been paid to the issue of measurement (see Chapter 2.2); the standardisation of data collection procedures (see Chapter 3.4); and the verification and testing of all data to ensure accuracy and consistency was achieved (see Chapter 4).

Initially, seven variables were identified as possible outcome measures, but during the course of the study an eighth variable was added to this number. Of these eight variables, it was concluded that no single measure was ideal. However, within the constraints of the procedures and methods of testing described in the previous chapters, four variables were considered to be sufficiently sensitive and reliable to merit consideration as instruments and, of these, three were identified as capable of measuring outcome following lower limb fracture. These three variables were: time to union, time to return to work and the ability to kneel 38 weeks following injury.

In addition to the ability to kneel, nine other functional variables were shown to be sufficiently sensitive and reliable to satisfy the requirements set for this study, and since all nine were significantly related to the ability to kneel, it was considered appropriate to advocate the use of any of these ten variables to assess functional recovery, providing that future investigators adopt the same procedures specified in this study. In fact, this proviso applies to the future use of every variable outlined in Chapter 3.4. Nevertheless, it was recognised that there were deficiencies in all these instruments, either because of the way in which data had been collected (ie retrospectively for the clinical data) or because the measures were insensitive to the needs of the group as a whole (ie the unemployed, people not requiring to kneel etc.). Therefore, it was considered judicious to advocate the use of more than one outcome measure in any one study and, preferably, to include physiological, socio-economic and functional measures in order to address both sides of the argument for measuring quantitative and qualitative end results.

Finally, it was appreciated that, in the hands of different investigators, the instruments described in this study may behave differently. Consequently, while there are grounds for recommending the cautious use of these tools, ideally their properties of measurement should be re-calculated for all investigators involved in every new data collection exercise.

7.1.4. Sound empirical description

The second aim of the study was to provide an accurate description of the patient population in terms of their clinical, socio-economic, psychological and functional characteristics. This aim was set in the knowledge that many descriptive studies had been published on this topic already. However, most of these studies have confined their attention to a limited number of clinical characteristics of fracture or circumstances of injury and have not attempted to describe a cross-section of patients at comparable stages during their recovery. For this reason, the descriptive data reported in Chapter 5 is unique in providing reliable, comparative information across a broad spectrum of clinical and rehabilitative variables for all subjects. Also, the procedures used to obtain these data have been standardised and tested for their accuracy and consistency and each variable has been defined explicitly so that these procedures may be replicated in the future (see Appendix II). However, it is emphasised that it would be preferable for the clinical data to be gathered prospectively by an independent assessor following standardised procedures.

Although the descriptive data raised many interesting issues in connection with the prevention of injury and the management and recovery of patients, one main conclusion was drawn from this exercise. It was concluded that clinical impressions concerning the time that fractures take to heal under natural conditions (ie when no or minimal intervention occurs) appear to be over-optimistic in relation to the accuracy of existing tests of union and the population variance.

Despite the diagnosis of a number of cases of "delayed" or "non-union", all the fractures in this series went on to unite. The median time for this event to be confirmed in subjects' hospital notes was 26 weeks and, whilst it is recognised that the sensitivity of this measure is in question (due to the vagaries of medical records and the time intervals between subjects' clinic appointments), it would appear that current estimates err on the side of being too short. In other words, it is possible that unrealistic expectations may have inflated the number of cases perceived as "difficult". This may have contributed to the controversy over when to intervene and what type of intervention to take. Certainly, it would seem that much of the descriptive data relating to patients' management and recovery confirmed this suspicion. For example, 16 weeks following injury, a third of all subjects had their fracture externally immobilised; a fifth of the group were dependent upon walking aids; and approximately half the group reported that they experienced pain at the fracture site when they were weight bearing on their injured leg. Just one third of working people were back at work at this point in time and most people were still having considerable difficulty with everyday functions such as walking extensively, crossing difficult ground or negotiating slopes and gradients.

Therefore, there may be a case for revising the time scales associated with fracture healing, as previously suggested in an editorial leader in the British Medical Journal in 1912 (Watson-Jones, 1943). Equally, there is a need to improve the accuracy of instruments for determining clinical and radiological union if this revision is to be based upon sound empirical data rather than clinical impression.

Until such time as a properly designed survey of natural fracture healing is undertaken, using appropriately sensitive, valid and reliable measures to determine equivalent end-points for a large number of cases of fracture, this issue will remain contentious because different perceptions of "normality" will prevail and will be used to justify different types of intervention.

Currently, there is no way of knowing whether any particular treatment is effective because, once performed, there is no way of knowing what might have happened otherwise. In the absence of normative data, one alternative way of gaining such knowledge is to conduct a clinical trial. Therefore, the last aim of this study was to demonstrate the kind of steps that would need to be taken in order to achieve this objective.

7.1.5. Research design and statistical analysis

The third and final aim of this study was to identify potentially important prognostic indicators which, in addition to being able to forecast recovery, might also need to be considered in the research design of a clinical trial. Two stages of analysis were conducted entailing the use of techniques of correlation and survival analysis.

The importance of controlling the clinical environment to minimise the effect of extraneous variables upon outcome has been noted in Chapter 1.3 in relation to previous attempts to classify diaphyseal fractures. Although classifications merely serve the purpose of organising descriptive data into classes on the grounds of some underlying rationale, many authors have tried to use classifications as a means for determining how variables, such as site of injury, effect outcome. Two of the more extreme examples cited classified fractures into three classes (Ellis, 1958a) and 108 classes (Kay et al, 1986), respectively.

However, there is not only disagreement over the number and nature of variables that need to be considered in this way, but also the exact direction of their influence. For example, Nicoll (1964) suggested that middle third fractures of the tibia had a poorer prognosis in terms of time to union, while Haines et al (1984) suggested the converse. These conflicting viewpoints are particularly unhelpful when attempting to design clinical trials and since it was not possible for clinicians to agree upon those variables that needed to be taken into consideration, a decision was taken to use statistical procedures to perform this function.

By a process of elimination attention was focussed upon a number of variables that correlated significantly with time to union, time to return to work and the ability to kneel 38 weeks following injury. Of these, severity was found to be associated with all three types of outcome and, therefore, it was strongly recommended that subjects entered into future experimental trials should be randomly allocated to "treatment" groups using a stratified random design to control for this effect. For cases of tibial fracture, it was recommended that consideration be given to controlling for the effects of fibular fracture as well when using time to union or time to return to work as measures of outcome.

During the course of performing these analyses, statistical techniques were used to exemplify the way in which *a priori* hypotheses could be tested in the context of an experimental trial or naturalistic survey. It was concluded that survival analysis may be very suitable for analysing time-based data relating to both union and return to work, particularly in view of its capability of taking into account censored values (ie data for individuals lost to follow-up or for whom the outcome has not occurred by the time of the analysis) and the influence of other factors, not controlled by the stratified random allocation of subjects to groups. However, it is recognised that techniques such as these are likely to prove unpopular with clinicians and some of the reasons why this may be so are discussed in the following section.

7.1.6. Professional conviction versus scientific uncertainty

One reason why clinicians may have been reluctant to take part in clinical trials is that, as a result of their training, surgeons are said to be "likely to have a particular philosophy based upon a dedication to certain techniques and procedures" (Rudicel and Esdaile, 1985) which they apply, discriminately, in what they consider to be the best interests of their patients. As these same authors point out, such a philosophy demands that surgeons hold **prior** beliefs about the benefits of certain procedures compared with others. In fact, historically, the practice paradigm of the medical profession is said to be authoritarian with medical care being administered through a chain of authority wherein the doctor is the principal decision-maker (Hoffmann, 1986). This means that members of the medical profession are trained to be decisive. But, the convictions defended by different doctors in a clinical situation are just as likely to undermine the objectivity required of them as scientific investigators and vice versa.

By contrast, scientists should not allow their personal beliefs and preferences to influence the way in which they investigate a problem - otherwise the conclusions they draw remain opinionated, at best, or may be erroneous, at worse. So, in an attempt to eliminate bias, scientists take great care to use methods, techniques and measures which are designed to minimise various sources of such error. For example, subjects entered into an experimental trial are randomly allocated to treatment groups to minimise suseptibility bias; ideally, trials are conducted single or double-blind(10) to reduce performance and detection biases; while attention is paid to the differential attrition of subjects from the groups to avoid potential transfer bias. In short, science is concerned with questioning the truth of specified hypotheses and reducing uncertainty about these truths by adopting methods which state explicitly how conclusions have been reached and the risk involved in having reached an incorrect conclusion from the data. Therefore, a professional philosophy that denies the existence of uncertainty in the first place, is unlikely to provoke believers into questioning what they already staunchly believe to be true. On the one hand, surgeons are required to make definitive judgements, while on the other hand they are required to be impartial observers. Since it has been said that "uncertainty is antithetical to surgical training" (Rudicel and Esdaile, 1985), it is possible that the roles of clinician and scientist cannot be combined very easily because of a conflict between professional conviction and scientific uncertainty.

7.1.7. Time constraints upon clinicians

Equally, it may be unreasonable to presume that clinicians have the time to conduct properly orchestrated prospective and experimental research in conjunction with their more pressing clinical commitments. The fact that clinicians are responsible overall for the care of patients means that this role must take precedence over a scientific interest in patients as subjects. However, the prioritisation of these responsibilities necessarily relegates research into a subsidiary task, undertaken by the industrious surgeon during spare moments, rather than conducted as a *raison d'etre*. Therefore, it is hardly surprising that the majority of orthopaedic studies addressing patient treatment have been undertaken retrospectively (when time has permitted) and have concentrated upon the description of procedures which the author(s) believe to be superior to available alternatives. What is surprising is that despite the division of opinion, questions have not been asked about the truth of (occasionally conflicting) assertions held by all experts.

However, it must be remembered that prospective studies and experimental trials can be extremely time consuming and that their success depends upon the total commitment and availability of individual fieldworkers to carry out standard procedures in a predetermined way, often over a considerable period of time. Due to the unpredictable nature of case-loads primarily arising from chance occurrences, clinicians practising in this speciality face particular difficulties when trying to allocate time to clinical and research duties during the same working hours. Inevitably, when necessessity arises, the demands of research must be compromised in the interest of ensuring that patient care is of the highest possible standard. For example, a subject assessment might have to be cancelled if the designated fieldworker/surgeon has to be in theatre at the time of the appointment. Clearly, the clinician cannot be as flexible as the full-time fieldworker: nor can junior doctors on a six month rotation be as dedicated as designated research staff, but this situation does little to benefit the quality of clinical research.

7.1.8. Lack of clinical research expertise

There is a third argument which states that because medical science is modelled predominantly upon the methods adopted by the basic sciences, surgeons may be unfamiliar with the methods of the social and behavioural sciences and, therefore, may be ill-equipped to investigate clinical problems. Not surprisingly, this type of argument has been proffered by social psychologists who have drawn attention to the "rather elementary nature" of many of the research guides written for medical readers and have cited this as an indication of a general lack of expertise (Lipton and Hershaft, 1985). The preponderance of descriptive and case-study type articles appearing in the literature would seem to support this observation and have led Goldstein to remark that "while many clinicians have come up with excellent research ideas, they generally lack the tools needed to implement them. These tools consist of expertise in research design, research planning, getting the plan implemented, analysing the obtained data and writing reports" (Lipton and Hershaft, *op cit,* p337).

To be fair, this comment might apply to the vast majority of members within any profession, academic or otherwise. With the exception of experienced statisticians, few individuals would claim to be sufficiently knowledgable in all aspects of research as not to require advice during the course of a research project. Needless to say, the criticism being made was not intended as a global condemnation of clinical research, but rather as a constructive argument in favour of clinicians balancing their existing knowledge about the methods of the basic biological sciences with those of the social and behavioural sciences.

7.2. Implications for the Future

Writing a decade ago White (1975) stated that:

> In this age of moon voyages and heart transplants, the orthopaedic surgeon faces a rather basic, but formidable question. Is it better to treat a healing bone by rigidly immobilising it or by allowing it to move? (1975, p279)

Although fundamental to the art of clinical practice, this question remains unanswered to this day. Is this situation likely to change?

7.2.1. Developments

At the time of writing, it is encouraging to be able to report that, as a direct result of this work, two prospective studies are currently underway and both are using measures, procedures and methodologies which have been based upon those outlined in the previous chapters.

The first study has been designed to test the predictive validity of a standardised technique of bone scanning for identifying tibial shaft fractures which do not unite by their 16th and 24th week following fracture. The main purpose of this research is to determine the accuracy of the scanning technique for making correct predictions about union so that, ultimately, these predictions may be used as the basis for a randomised prospective trial of the efficacy of early bone grafting in cases of fracture predicted to take longer than 16 weeks to unite.

The second study has been designed as a prospective, comparative trial to investigate the relative benefit of one form of external fixation versus one form of internal fixation for the treatment of diaphyseal fracture of the tibia. In this study, the null hypothesis being tested is that there is no difference in time to union, time to return to work and the ability to kneel 38 weeks following injury for subjects treated with the method of external fixation and those treated with the method of internal fixation.

Though a laudable aim, the implicit value judgement being made in the design of this second study is that both treatments are superior to no/minimal treatment techniques and, therefore, this study does not address the fundamental question of whether intervention serves any purpose. Just because one treatment may be demonstrated to be significantly better than the other for a particular outcome does not imply its overall supremacy. In reality, it could just be the better of two inferior treatment procedures for a specific outcome. Alternatively, if no difference is found between the two procedures there is still uncertainty as to whether this is because the procedures produce equally good or equally bad results. Hence, despite these two developments there are more urgent problems which require attention and these are addressed in the next sub-section.

7.2.2. Main recommendations

The are four main recommendations which result from this study and these are :

- (1) It is recommended that immediate attention be given to improving and testing the sensitivity and the reliability of **clinical** and **radiological** measures of union.

- (2) Contingent upon this development, it is recommended that a large scale survey of the natural healing process and recovery made by patients be conducted in order to gather normative data on fracture healing and to enable agreement to be reached on appropriate ways of defining and classifying diaphyseal fractures of the tibia.

- (3) It is recommended that a clinical trial be conducted to evaluate the benefit of conservative versus operative procedures for stabilising tibial shaft fractures. This should be viewed as a priority before other comparative studies are undertaken and, if contentious, should be based upon a "randomised surgeon design" (Rudicel and Esdaile, 1985) to minimise the ethical objections held by different surgeons dedicated to the opposing techniques.

- (4) Finally, it is recommended that serious consideration be given to developing the appropriate resources and expertise necessary to conduct clinical orthopaedic research and that this should be based on the methods of the social and behavioural sciences as well as those of the basic biological sciences.

7.2.3. The Future

Clinically, there can be no doubt that there has been widespread concern over the length of time which some diaphyseal fractures have taken to unite and that this has been evident in the case of tibial fractures especially. However, despite the attention of a great many eminent clinicians over the past ten years and more, there remains much dispute over the treatment and management of such fractures. Had this dissensus been minimal there would have been little cause to examine the matter further. Nevertheless, this was not the case and since the furtherance of knowledge through the methods of authority, rationale and intuition have not been able to clarify the problem, it was befitting to call upon the methods of science to do so. Therefore, this research may be seen to have advanced the discussion by offering a means whereby attention could be directed towards aspects of the existing debate which could be substantiated "beyond reasonable doubt" (Hampton, 1987).

The disadvantage of knowledge acquired through methods of authority, rationale and intuition is that unless the evidence is overwhelmingly in favour of one or other of the arguments being put forward, different experts are likely to hold idiosyncratic opinions according to their particular beliefs and expertise. Furthermore, because clinical education is modelled upon authoritarian lines, with different schools of thought perpetuating their own professional credos, there is a tendency towards the polarisation of opinion. Sometimes to the dismay of a minority of subjects entered into this study, these opinions were actively contested by colleagues favouring alternative procedures. Yet, although clinical opinion may be challenged, clinical views are rarely overturned simply because another clinician holds an opposing view. The more complex the problem, the more diverse the solutions and the more heated the debate.

By comparison, the methods of science attempt to promote a collective wisdom by developing a quantitative basis for what constitutes "reasonable doubt" in relation to the acceptance of knowledge. Of course, the methods of science are not infallible - studies can be badly designed, inaccurate data can be gathered, inappropriate statistical procedures can be used, wrong conclusions can be drawn and science can be applied wantonly. For example, it would be a waste of resources to demonstrate the benefits of antiseptic surgery scientifically when the benefits are accepted already. Frequently, it is alleged that the methods of science state the obvious, but, in medical research, this allegation may be attributed to what Coleman (1977) has described as the professional defensiveness of physicians and surgeons. Indeed, Soffer has observed a lack of self-criticism in medical knowledge and the tendency for medical myths and controversies to be perpetuated in the literature due to a reliance upon descriptive reporting (Lipton and Hershaft, 1985). Nevertheless, this lack of self-criticism is not unique to the medical profession and is said to typify the development of science within any profession (Kuhn, 1970). Yet, in view of the profound implications of medical knowledge upon patients, their families and the community at large, it is considered that the call made by White (1975) to apply the methods of science to the subject of how best to treat fractures is long overdue. It is hoped that this study provides the impetus for this to happen.

APPENDICES

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I. Notes

(1) In the context of this study the following definitions have been adopted in accordance with those specified in the ICIDH (WHO, 1980):

- Impairment: any loss or abnormality of psychological, physiological or anatomical structure or function.
- Disability: any restriction or lack (resulting from an impairment) of ability to perform an activity in the manner or within the range considered normal for a human being.
- Handicap: a disadvantage for a given individual, resulting from an impairment or a disability, that limits or prevents the fulfilment of a role that is normal (depending upon age, sex and social and cultural factors) for that individual.

(2) See the ICD Chapter XVII Injury and Poisoning, Fracture of the Lower Limb numbers 821.0 to 821.3 and 823.0 to 823.3, pp 480-481

(3) Presentation to the "At Home" meeting, Department of Orthopaedic Surgery, University of Edinburgh, December 1984.

(4) Data supplied by the Information and Statistics Division of the Common Services Agency of the Scottish Health Service.

(5) Presentation by Professor Hughes to the Association of British Insurers, Princess Margaret Rose Orthopaedic Hospital, November 1985.

(6) A distinction is made between "controlled" and "comparative" trials. In the present context, a controlled trial is defined as a comparison between an experimental group (eg patients undergoing intramedullary nailing) and one receiving minimal intervention (ie cast/traction). Although, ideally, a control group should receive no treatment at all, it would be unethical to leave a fractured tibia or femur totally unsupported. Hence, the minimal treatment for these fractures is considered to be the application of a cast/traction etc. This would be the best comparison one could make in order to say whether the results obtained from intramedullary nailing, for example, were better than minimal methods of treatment and so argue a case for surgical intervention.

A comparative trial makes the basic assumption that the treatments being compared are better than doing nothing (ie minimal treatment) and, therefore, asks the question as to which is the best procedure. Unfortunately, if the results of a comparative trial show no difference between the results for the groups (an even when they do), it can still be argued that intervention may have been unnecessary.

(7) Although 70% agreement and a correlation co-efficient of 0.70 may appear to be similar, it should be noted that they are not equivalent values. For example, later in Table 10 (see Chapter 4.2) only 67% agreement was achieved between two raters coding the number of people reported to be dependent upon each of nine subjects. However, the corresponding Pearson's correlation co-efficient for these data was $r = 0.93$, indicating that, even though differences occurred, the size of these differences was small. Conversely, 80% agreement was achieved between two raters for the measurement of real shortening taken from five subjects' limbs. The corresponding Pearson's correlation co-efficient for these data was $r = 0.61$ (see Table 16): In this instance, the raters disagreed on only one case, but the size of this difference was sufficiently large to reduce "r" below the reliability criterion required by this study. Since the calculation of each statistic depended upon different factors, such as the sample size and/or the magnitude of error, it was not possible to select exactly equal values for the two methods of assessing reliability.

(8) For example, subjects with higher external scores were more likely to have strongly agreed with the statement "I can only do what my doctor tells me to do".

(9) *Post hoc* or *a posteriori* comparisons are those which are not planned prior to looking at the data - *a posteriori* meaning "after the fact". As a consequence of this, care must be taken not to make Type 1 errors (ie rejection of the null hypothesis when it is true).

(10) In an experimental trial, it is customary that neither the investigator nor the subject should be aware of the experimental condition undergone by the subject (a so-called double-blind study). Alternatively, only an impartial assessor may be unaware of the experimental condition undergone by subjects (a single-blinded study). However, in a surgical trial, it is not possible to keep

the surgeon investigator "blinded" and it is unlikely that the patient, or an impartial assessor, would remain uninformed for long even if this was intended.

II. Research Instruments

II.I. Admission Data Schedule

University
Department of Orthopaedic Surgery
&
Rehabilitation Studies Unit

FOR OFFICE USE 101

ADMISSION DATA

Subject no. 1 2 3 4

Ward: Date of birth: Age:

Hospital no.: .... Sex: M 1 F 2 5

Date of admission: mth 6 7

at hrs 8 9

Day of the weeks: (circle) 1 M 2 T 3 W 4 Th 5 F 6 S 7 Su day 10

Date of discharge: hospital

treatment

Consultant: ....

Leg involved: R 1 L 2 FEMUR 1 TIBIA 2 11 12

Other details: ....
....
....
....

n/a 8
n/k 9

FOR OFFICE USE

INITIAL FRACTURE CLASSIFICATION

Severity:

- simple [1]
- compound [2] — grade
- not known [9]

Site:

- upper 33% length [1]
- mid 34-66% length [2]
- lower 67% + length [3]
- not known [9]

13 14

15

Initial displacement:

- none [1]
- less than 50% [2]
- 50% or more [3]
- not known [9]

Angulation:

(specify in degrees) $^{\circ}$

16 18

19

Pattern of fracture:

- transverse (less than 20° angle) [1]
- oblique (20° angle or greater) [2.]
- spiral [3]
- double (any combination) [4]
- comminuted (1 or more fragments) [5]
- not known [9]

20

Degree of comminution 'Hansen 1984):

- I (1 small fragment) [1]
- II (50% cortex intact) [2]
- III (less than 50% cortex intact) [3]
- IV (no abutment of cortices) [4]
- not known [9]

n/a 8

21

Velocity of injury:

- low. [1]
- high [2]
- not known [9]

Associated fibular fracture:

- no
- yes — same level / diff level / n/k
- n/a
- n/k

22 23 24

FOR OFFICE USE

Associated injuries:

	no	yes	not known	
skin injury/deficit	1	2	9	25
neurological deficit				26
tendonous injury				27
ligamentous injury				28
vascular injury				29
other (specify)	1	2	9	30

....

OTHER INJURIES (in addition to above)

List other main injuries ....

....

Summary table of other injuries:

	not applic	#	disloc	vasc	neuro	con-cuss	n/k	
head	8	1			4		9	31
upper limb: ipsilat.	8	1	2	3	4		9	32
contralat.								33
lower limb: ipsilat.								34
contralat.								35
spine								36
pelvis								37
other (specify)	8	1	2	3	4		9	38

....

KNOWN MEDICAL HISTORY

Existing medical conditions prior to admission:

none	1
yes	2 →
not known	9

cardiac	0	sensory	5
respir.	1	psychol.	6
locom./skeletal	2	other (specify)	7
C.N.S.	3	....	
endocr.	4	not known	9

39

40

n/a 8

FOR OFFICE USE

PERSONAL DETAILS (patient notes)

Age at time of fracture: ☐☐ yrs ☐☐ mths — yrs 41 42 ☐☐

Marital status:

single	1 ☐	
married/common law partner	2 ☐	
separated/divorced	3 ☐	
widowed	4 ☐	43 ☐

Occupation (specify) OPCS:

.... n/a 888 n/k 999 — 44 45 46 ☐☐☐

Social class, OPCS:

I	professional	0 ☐	
II	intermediate	1 ☐	
III	skilled, non-manual	2 ☐	
III	skilled, manual	3 ☐	
IV	semi-skilled	4 ☐	
V	unskilled	5 ☐	
	forces	6 ☐	
	other	7 ☐	47 ☐

Alcohol consumption:

.... no mention 0; mention in notes 1 — 48 ☐

Residence:

	Permanent	Current (if different)	
City of Edinburgh	0 ☐	☐	
Midlothian	1 ☐	☐	
East Lothian	2 ☐	☐	
West Lothian	3 ☐	☐	
Forth Valley	4 ☐	☐	
Fife	5 ☐	☐	
Borders	6 ☐	☐	
Other (specify)	7 ☐	☐	49 ☐

n/a 8
n/k 9

FOR OFFICE USE

INJURY DETAILS (patient interview)

Is the fracture a new injury ?

no, refracture [1]

yes [2] — 50 [ ]

Where did the injury occur ?

at home [1]

at work [2]

sports injury (specify) [3] ....

R.T.A. [4]

other (specify) [5] — 51 [ ]

....

Was this as a -

pedestrian [1] } Go to next page

cyclist [2]

on moped [3] } Continue below

on m/bike [4]

in car/van [5] — 52 [ ]

Were you the -

driver [1]

passenger [2] — 53 [ ]

Was a seat belt being worn ?

not applic. [1] (vehicle not equiped)

no [2]

yes [3] — 54 [ ]

Seat in vehicle?

front seat [1]

back seat [2] — 55 [ ]

n/a 8

n/k 9

FOR OFFICE USE

Circumstances of injury -

slip on slippery surface	1	
trip/fall (ground level)	2	
fall from a height	3	
direct violence (person)	4	
direct violence (object)	5	
other (specify)	6	56

....

Other details...

....

....

HOME CIRCUMSTANCES

With whom do you live at home ?

alone	1	
with parents/older relatives with or without others	2	
with spouse/partner with or without children/others	3	
with child/children only	4	
with siblings only	5	
with other relatives (sister brother etc.)	6	
with friends	7	57

Total number of people in the household: (including patient) no. 58 59

Do you have any dependents ?

no 1

yes 2 → Are they ....?

children only	1	60
adults only	2	
both	3	61

n/a 8
n/k 9

FOR OFFICE USE

Dependents continued.

How many dependents have you ?

no — 62 63

What type of accommodation do you live in ?

flat, ground level 1
flat upstairs/maisonette 2
house, one level/bungalow 3
house, internal stairs 4
other (specify) 5
....

64

Is there a lift ?

no 1
yes 2

65

Do you own your own home ?

yes, privately owned self/family 1
no, rented from local authority 2
no, rented from other than L.A. 3
no, occupied by employment 4
no, other (specify) 5
....

66

EMPLOYMENT

Prior to injury, were you in paid employment ?

yes, in full-time employment 1
yes, in part-time employment 2
no, unemployed, seeking work 3
no, unemployed not seeking work 4
no, retired/early retirement 5
no, housewife 6
no, full-time student 7

n/a 8
n/k 9

67

FOR OFFICE USE

Employment continued.

If in paid employment, how many years have you been in your present job ? (n.b. if more than one job is held enter years for all jobs)

actual no. years ☐☐ yrs ☐☐ 68-69

actual no. years ☐☐ yrs ☐☐ 70-71

....if less than 1 year specify approx. n/a 88

number of months .... code 01

Please describe the type of work which you do: ....

....

....

If married or living with a partner, does your wife/husband work ?

no 1

yes 2 → Is this.......?

n/a 8

part-time 1

full-time 2

72 ☐

73 ☐

PRE-INJURY ACTIVITY

How easily were you able to walk prior to this injury ?

no problem 1

some restriction/difficulty 2

severely restricted 3

(unable to walk 100 yards)

74 ☐

Did you regularly use a walking aid ?

no 1

yes (specify) 2

....

75 ☐

n/a 8
n/k 9

FOR OFFICE USE

2

Pre-injury activities continued.

How frequently during the month before your injury did you do any of the following activities ....?

	never	less than once a week	once a week	more than once a week	
shopping	1	2	3	4	1
visiting friends, relations	1	2	3	4	2
social clubs, pubs, centres					3
leisure pursuits (excl. sports)	1	2	3	4	4
appointments (GP, hair)					5
entertainments (cinema etc.)					6
other (specify)	1	2	3	4	7
....				Total	8 – 11

Prior to your injury, how frequently did you use any of the following forms of transport as a **passenger** ....?

	never	less than once a week	once a week	more than once a week	
bus	1	2	3	4	12
train					13
moped/scooter					14
motorbike					15
car, van	1	2	3	4	16
other (specify)					17
....				Total	18 – 21

AND.............. as a **driver** ....?

	never	less than once a week	once a week	more than once a week	
bicycle	1	2	3	4	22
moped/scooter					23
motorbike					24
car, van					25
other (specify)					26
....				Total	27 – 30

n/a 8
n/k 9

FOR OFFICE USE

Pre-injury activities continued.

How frequently did you play any of the following sports in the month before your injury (or during the last season) ....?

	never	less than once a week	once a week	more than once a week	level of involvement	
rugby	1	2	3	4		31
football						32
skiing						33
contact sports						34
....						
racket sports	1	2	3	4		35
....						36
....						
other ball games						37
other (specify)	1	2	3	4		38
....						39 40 41 42

Total
n/a 8
n/k 9

What hobbies, interests or other activities do you pursue in your leisure time ?

....

....

....

Please describe any household chores which you perform ?

....

....

....

SIGNATURE.................................. DATE ....

II.II. Follow-up Data Schedule (16 & 38 weeks)

FOR OFFICE USE 301

Mobilisation

Is the fractured limb still immobilised?

- no [1]
- yes [2] →
  - long-leg cast [1]
  - P.T.B. [2]
  - other (specify) [3]
  - ....

1 [ ]

2 [ ]

Is the patient walking?

- no, on bed-rest [1]
- yes, non-weight bearing [2]
- yes, partial-weight bearing [3]
- yes, full-weight bearing [4]

3 [ ]

If patient is full-weight bearing is gait....?

- normal [1]
- slight limp [2]
- abnormal (specify) [3]
- ....

4 [ ]

Do you have any pain at the moment?

- no [1]
- yes [2] → ask patient to complete appropriate pain questionnaire

5 [ ]

Do you feel pain when you are walking?

- pain free [1]
- occasional pain [2]
- usually painful [3]

6 [ ]

Do you feel pain when you are resting?

- no [1]
- occasionally [2]
- yes [3]

7 [ ]

n/a 8

FOR OFFICE USE

Is pain affecting your sleep?

no [1]

yes [2] 8

As a result of the injury, how dependent are you upon other people?
Please describe things with which you need help.

....

....

....

Employment

Occupational outcome: [1] still off work due to accident
(answer next question)

[2] returned to work date [| | | | |]
(miss next question)

[3] seeking/out of work) Go on to next section

[4] economically inactive (student housewife)) Go on to next section 9

Is your job still available?

no [1]

yes [2]) Go on to next section 10

n/a [9] If no, specify circumstances

....

....

....

Is your job...?

[1] full-time with same employer [1]

[2] part-time another employer [2] 11 12

n/a 8
n/k 9

FOR OFFICE USE

If with the <u>same</u> employer, is/was your job modified in any way on your return?

no [1]

yes (specify) [2] 13 [ ]

....

....

Is/was a change of job involved?

no [1]

yes (specify) [2] 14 [ ]

....

....

If you are with another employer, state reasons for the change and describe the new job?

....

....

....

....

Do you have any persistant problems at work?

no [1]

yes (specify) [2] 15 [ ]

....

....

What procedures were followed on your return to work (specify)?

....

....

....

....

n/a 8
n/k 9

FOR OFFICE USE

How do you feel about the timing of your return to work? Was it.....

too early	1	
about right	2	
later than necessary	3	16

Rehabilitation Services

Have you had any contact with rehabilitation professionals during your recovery to date?

	No	Yes	
social worker	1	2	17
occupational therapist			18
physiotherapist			19
remedial therapist			20
general practitioner			21
homeopath			22
other alternative medical specialist	1	2	23
sports coach etc.			24
other (specify)			25

....

Have you had any contact with vocational rehabilitation personnel to date?

	No	Yes	
E.R.O.	1	2	26
D.R.O.			27
other (specify)			28

....

n/a 8
n/k 9

FOR OFFICE USE

Have you had any contact with work personnel during your period off sick?

	No	Yes	
Occupational health personnel	1	2	29
Personnel management			30
Line management			31
T.U. representative	1	2	32
Co-workers			33
Other (specify)			34

....

Post-Injury Activity

Have you resumed all your former social activities?

no	1	35
yes	2	

If no, what are you still unable to do?

....

....

....

During the last month, how frequently have you done any of the following activities?

	never	less than once per week	once per week	more than once per week	
Shopping	1	2	3	4	36
Visting friend/relations					37
Social clubs/pubs, centres					38
Leisure pursuits (excluding sports)	1	2	3	4	39
Appointments (GP, hair)					40
Entertainments (cinema etc)					41
Other (specify)	1	2	3	4	42

....

43 44 45 46

n/a 8

n/k 9

FOR OFFICE USE

Have you resumed all the former hobbies, interest and leisure activities which you wish to pursue?

no [1]

yes [2] 47 [ ]

If no, what are you still unable to do?

....

....

....

What hobbies, interests or activities do you pursue in your leisure time?

....

....

Have you resumed playing all those sports which your formerly participated in?

never play [8]

no, unable [1]

no, out of season [2] 48 [ ]

yes [3]

What are you still unable to do?

....

....

....

What sports have you played since your injury? (Write none if appropriate)

....

....

....

n/a 8
n/k 9

FOR OFFICE USE

How frequently have you played any of the following sports in the last month (for seasonal games note whether patient intends to start playing next season)?

	never	less than once a week	once a week	more than once a week	level of involvement	
rugby	☐ 1	☐ 2	☐ 3	☐ 4		49 ☐
football	☐	☐	☐	☐		50 ☐
skiing	☐	☐	☐	☐		51 ☐
contact sports	☐	☐	☐	☐		52 ☐
racket sports	☐ 1	☐ 2	☐ 3	☐ 4		53 ☐
....	☐	☐	☐	☐		54 ☐
other ball games	☐	☐	☐	☐		55 ☐
other(specify)	☐ 1	☐ 2	☐ 3	☐ 4	n/a 8 n/k 9	56 ☐
					Total	57 58 59 60 ☐☐☐☐

Are you still able to use all the forms of transport which you formerly used as a passenger?

no ☐ 1

yes ☐ 2

If no, what are you still unable to use?

....

....

61 ☐

....and as a driver?

don't drive ☐ 8

no ☐ 1

yes ☐ 2

If no,what are you still unable to do?

....

....

62 ☐

FOR OFFICE USE

During the last month how frequently have you used any of the following forms of transport as a passenger?

	never	less than once per week	once per week	more than once per week	
bus	1	2	3	4	63
train					64
moped/scooter					65
motorbike					66
car/van	1	2	3	4	67
other(specify)					68
....					
				TOTAL	69 70 71 72

....and as a driver?

	never	less than once per week	once per week	more than once per week	
bicycle	1	2	3	4	73
moped/scooter					74
motorbike					75
car/van	1	2	3	4	76
other(specify)					77
....				TOTAL	1 2 3 4

n/a 8
n/k 9

Have you resumed <u>all</u> your household chores?

no 1
yes 2

If no, what are you still unable to do?

....

....

....

5

Please describe any household chores which you perform?

....

....

....

FOR OFFICE USE

Examination

INSTRUCTIONS:

For all variables: compare # site with equivalent areas on contralateral limb.

Tenderness: palpate

Muscle wasting: compare calf measurements at the level of maximum bulk.

	no	yes			
Deformity(visual)	1	2			6
Tenderness					7
	less than 2cms	2cm or more	GIRTH OF AFFECTED LEG	GIRTH OF UNAFFECTED LEG	
Muscle wasting	1	2	....	....	8

(Where cast prevents examination - code 9)

Neurological weakness

(through critical range or obtainable range where limitations present)

	no	yes	not known	
knee flexors	1	2	9	9
knee extensors				10
dorsiflexors				11
plantarflexors				12
(If leg immobilised -code 9)				
hip flexors				13
hip extensors	1	2	9	14

Real shortening

(compare affected with non-affected limb - Read, 1984)

Measure from greater trochanter to lateral aspect of knee joint or lateral aspect of knee joint to lateral malleolus-femoral/tibial.

affected limb ....cms

unaffected limb.......................cms

difference ....cms

diff cms 15 16 17

n/a 8
n/k 9

FOR OFFICE USE
310

Range of Movement

INSTRUCTIONS:
Use one universal goniometer for all measurements. Standardise starting positions and procedures a far as possible. Take 3 recording for each range.

	affected leg	unaffected leg	mean % affected/unaffected	
Hip flexion: (0/90^{0})	....	....		
	....	....		18 19 20
	....	....	....	
Hip extention:	....	....		
	....	....		21 22 23
	....	....	....	
Knee flexion: (45^{0})	....	....		
	....	....		24 25 26
	....	....	....	
Knee extension: (95/100^{0})	....	....		
	....	....		27 28 29
	....	....	....	
Dorsiflexion: (30^{0})	....	....		
	....	....		30 31 32
	....	....	....	
Plantarflexion: (20^{0})	....	....		
	....	....		33 34 35
	....	....	....	
Subtalar: inversion	....	....		
	....	....		36 37 38
	....	....	....	
eversion	....	....		
	....	....		39 40 41
	....	....	....	

(where cast prevents examination Code 9)

Functional Movements

I am interested in whether you are **able** to perform certain movements or maintain certain positions which you **need** to carry out your job and/or other household and pastime activities.

Consider each of the following items in terms of whether it is an **essential** part of your job or other activities, then consider the **ease** with which you feel you are currently able to perform the movement or maintain the position.

FOR OFFICE USE
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Functional Movements	NEC. FOR: WORK / OTHER	CURRENT ABILITY: able	difficult	unable		
Awkward postures/balance	1 ☐ 2	1 ☐	2 ☐	3 ☐	42 ☐	43 ☐
Prolonged standing	☐	☐	☐	☐	44 ☐	45 ☐
Prolonged sitting	☐	☐	☐	☐	46 ☐	47 ☐
Prolonged kneeling	☐	☐	☐	☐	48 ☐	49 ☐
Stooping/crouching/squatting	1 ☐ 2	1 ☐	2 ☐	3 ☐	50 ☐	51 ☐
Extensive walking	1 ☐ 2	1 ☐	2 ☐	3 ☐	52 ☐	53 ☐
Slopes/gradients	☐	☐	☐	☐	54 ☐	55 ☐
Traversing difficult terrains	1 ☐ 2	1 ☐	2 ☐	3 ☐	56 ☐	57 ☐
Running	☐	☐	☐	☐	58 ☐	59 ☐
Jumping	1 ☐ 2	1 ☐	2 ☐	3 ☐	60 ☐	61 ☐
Climbing stairs	☐	☐	☐	☐	62 ☐	63 ☐
ladders	☐	☐	☐	☐	64 ☐	65 ☐
nat. objects	1 ☐ 2	1 ☐	2 ☐	3 ☐	66 ☐	67 ☐
Lifting/carrying	1 ☐ 2	1 ☐	2 ☐	3 ☐	68 ☐	69 ☐
Transfers: sit/st	☐	☐	☐	☐	70 ☐	71 ☐
st/crouch or kneel	☐	☐	☐	☐	72 ☐	73 ☐
sit, crouch, kneel/ground	1 ☐ 2	1 ☐	2 ☐	3 ☐	74 ☐	75 ☐
Transport: public	☐	☐	☐	☐	76 ☐	77 ☐
private	1 ☐ 2	1 ☐	2 ☐	3 ☐	78 ☐	79 ☐
Foot/leg controls	1 ☐ 2	1 ☐	2 ☐	3 ☐	80 ☐	1 ☐
Foot/leg actions (bicycling, kicking etc.)	1 ☐ 2	1 ☐	2 ☐	3 ☐	2 ☐	3 ☐

Summary:		
	No. of necessary functions/able	☐☐ 4-5
	No. of necessary functions/difficult	☐☐ 6-7
	No. of necessary functions/unable	☐☐ 8-9
	No. of work functions/able	☐☐ 10-11
	No. of work functions/difficult	☐☐ 12-13
	No. of work functions/unable	☐☐ 14-15

na/0
nk/9

Patients' Opinion

How satisfied are you with your recovery to date?

extremely dissatisfied	very dissatisfied	moderately dissatisfied	not sure	moderately satisfied	very satisfied	extremely satisfied	16
☐	☐	☐	☐	☐	☐	☐	☐

Comments:

....

....

....

....

....

....

....

....

....

....

....

....

....

....

SIGNATURE .... DATE ....

FOR OFFICE USE

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Insurance

Personal insurance policies

none	1	
sickness/accident	2	
life/other	3	
both	4	17

Is a personal injury claim being made?

no	1	
yes	2	18

permanent health	1	
personal accident	2	
employers' liability	3	
motor	4	
public liability	5	
other (specify)	6	19

....

If yes, at what stage is the claim?

considering claiming	1	
consultation with solicitor	2	
claim lodged	3	
writ	4	
medical examination(s)	5	
claim settled	6	20

Household Finances

Financial circumstances during period of incapacity?

reduced income	1	
income maintained	2	
income increased	3	21

RETURN TO WORK:
No. weeks post-injury

wks 22-23

n/a 8
n/k 9

II.III. Questionnaire One

SUBJECT NO..........

QUESTIONNAIRE 1

PATIENTS NAME .... **DATE...............** **TIME .... AM/PM**

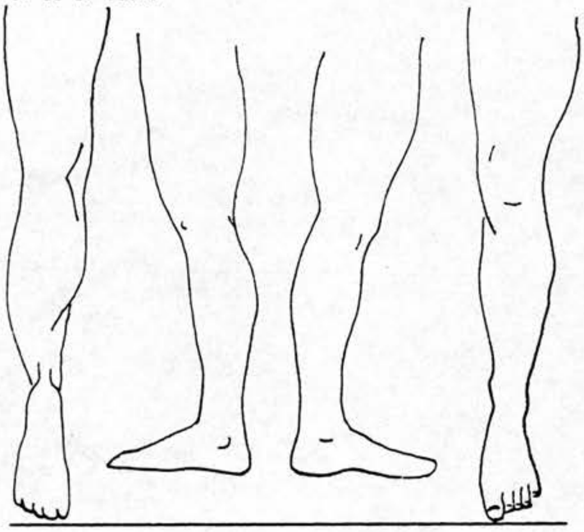
ANALGESIC(S) .... **DOSAGE ....** **TIME GIVEN ....AM/PM**

ANALGESIC TIME DIFFERENCE (HRS): **+½ +1 +2 +3** (circle as appropriate)

This questionnaire has been designed to tell us about your pain. If you have no pain at present tick this box ☐ Please complete the questionnaire for pain felt in you **lower leg only.** If you have pain elsewhere please ask for a second form.

Where is the pain?

Please mark, on the drawings below, the areas where you feel pain. Put an **E if external**, and **I if internal** or **EI if both.**



How does your pain change with time?

Circle **ONE** of the following groups of words.

continuous, steady, constant

rhythmic, periodic, intermittant

brief, momentary, transient

What does your pain feel like?

Some of the words below describe your **present** pain. **Only** circle words which best describe your pain and choose **only ONE** word from each group.
Leave out groups which are not suitable.

Flickering Quivering Pulsing Throbbing Beating Pounding	Tugging Pulling Wrenching	Sickening Suffocating	Tight Numb Drawing Squeezing Tearing
Jumping Flashing Shooting	Hot Burning Scalding Searing	Fearful Frightful Terrifying	Cool Cold Freezing
Pricking Boring Drilling Stabbing Lancinating	Tingling Itchy Smarting Stinging	Punishing Gruelling Cruel Vicious Killing	Nagging Nauseating Agonizing Dreadful Torturing
Sharp Cutting Lacerating	Dull Sore Hurting Aching Heavy	Wretched Blinding	
Pinching Pressing Gnawing Cramping Crushing	Tender Taut Rasping Splitting	Annoying Troublesome Miserable Intense Unbearable	
	Tiring Exhausting	Spreading Radiating Penetrating Piercing	

How strong is your pain?

The following 5 words represent pain of increasing intensity:

1 mild
2 discomforting
3 distressing
4 horrible
5 excrutiating

Answer each question below by writing the number corresponding to the appropriate word in each box.

Which word describes your pain right now? ☐
(if no pain write '0')

Which word describes it at its worse? ☐

Which word describes it at its least? ☐

Accompanying symptoms?

Do you experience any of the following?
Circle **all** appropriate responses.

Nausea Headache Dizziness
Drowsiness Constipation Diarrhea

Is your sleep?

Good Fitful Can't sleep

Is your food intake?

Good Some Little None

Activity?

Good Some Little None

II.IV. Questionnaire Two

QUESTIONNAIRE 2

This questionnaire is designed to find out what different people think about health-related issues.
Read each sentence carefully and then circle the number which is nearest to our own opinion.
The more strongly you agree with a sentence, the higher the number you circle. The more strongly you disagree with a sentence, the lower the number you circle.
Please answer every sentence and circle only one number per item.
There are no right or wrong answers.

---

	strongly disagree	moderately disagree	slightly disagree	slightly agree	moderately agree	strongly agree
1. If I take care of myself, I can avoid illness.	1	2	3	4	5	6
2. Whenever I get ill it is because of something I've done or not done.	1	2	3	4	5	6
3. Good health is largely a matter of good fortune.	1	2	3	4	5	6
4. No matter what I do, if I am going to get ill I will get ill.	1	2	3	4	5	6
5. Most people do not realise the extent to which their illnesses are controlled by accidental happenings.	1	2	3	4	5	6
6. I can only do what my doctor tells me to do.	1	2	3	4	5	6
7. There are so many strange diseases around that you never know how or when you might pick one up.	1	2	3	4	5	6
8. When I feel ill, I know it is because I have not been getting proper exercise or eating right.	1	2	3	4	5	6
9. People who never get ill are just plain lucky.	1	2	3	4	5	6
10 People's ill health results from their own carelessness.	1	2	3	4	5	6
11 I am directly responsible for my health.	1	2	3	4	5	6

II.V. Questionnaire Three

QUESTIONNAIRE 3

1. WORK

For some people work is just a means to get money, something they have to put up with. For others, work is the centre of their life, something that really matters. Whether you are actually in a paid job does not matter.

Please answer the statements below by circling the number which corresponds nearest to your own opinion.

The more strongly you agree, the higher the number you circle. The more strongly you disagree, the lower the number you circle.

PLEASE ANSWER EVERY SENTENCE AND CIRCLE ONLY ONE NUMBER PER ITEM.

There are no right or wrong answers.

	No, I strongly disagree	No, I disagree quite a lot	No, I disagree just a little	I'm not sure about this	Yes, I agree just a little	Yes, I agree quite a lot	Yes, I strongly agree
1. Even if I won a great deal of money on the pools I would continue to work somewhere.	1	2	3	4	5	6	7
2. Having a job is very important to me	1	2	3	4	5	6	7
3. I should hate to be on the dole	1	2	3	4	5	6	7
4. I would soon get bored if I had no work to do	1	2	3	4	5	6	7
5. The most important things that happen to me involve work	1	2	3	4	5	6	7
6. If unemployment benefit was really high I would still prefer to work	1	2	3	4	5	6	7

	No, I strongly disagree	No, I disagree quite a lot	No, I disagree just a little	I'm not sure about this	Yes, I agree just a little	Yes, I agree quite a lot	Yes, I strongly agree
Answer the next statements in relation to your current (or last job if you are not in a paid job at present)							
7. I feel a sense of personal satisfaction when I do this job well	1	2	3	4	5	6	7
8. My opinion of myself goes down when I do this job badly	1	2	3	4	5	6	7
9. I take pride in doing my job well	1	2	3	4	5	6	7
10. I feel unhappy when my work is not up to my usual standard	1	2	3	4	5	6	7
11. I like to look back on the day's work with a sense of a job well done	1	2	3	4	5	6	7
12. I try to think of ways of doing my job effectively	1	2	3	4	5	6	7

2. SATISFACTION

The next set of statements deal with various aspects of your job and life in general. I would like you to indicate how satisfied or dissatisfied you feel with each statement.

The more satisfied you feel, the higher the number you circle. The more dissatisfied you feel, the lower the number you circle.

PLEASE ANSWER EVERY SENTENCE AND CIRCLE ONLY ONE NUMBER PER ITEM.

Again, there are no right or wrong answers.

	I'm extremely dis-satisfied	I'm very dis-satisfied	I'm moderately dis-satisfied	I'm not sure	I'm moderately satisfied	I'm very satisfied	I'm extremely satisfied
Answer the next statements in relation to your current job (or last job if you are not in a paid job at present)							
13. The physical work conditions	1	2	3	4	5	6	7

	I'm extremely dis-satisfied	I'm very dis-satisfied	I'm moderately dis-satisfied	I'm not sure	I'm moderately satisfied	I'm very satisfied	I'm extremely satisfied
14. The freedom to choose your own method of working	1	2	3	4	5	6	7
15. Your fellow workers	1	2	3	4	5	6	7
16. The recognition you get for good work	1	2	3	4	5	6	7
17. Your immediate boss	1	2	3	4	5	6	7
18. The amount of responsibility you are given	1	2	3	4	5	6	7
19. Your rate of pay	1	2	3	4	5	6	7
20. Your opportunity to use your abilities	1	2	3	4	5	6	7
21. Industrial relations between management and workers in your firm or place of work	1	2	3	4	5	6	7
22. Your chance of promotion	1	2	3	4	5	6	7
23. The way your firm is managed	1	2	3	4	5	6	7
24. The attention paid to the suggestions you make	1	2	3	4	5	6	7
25. Your hours of work	1	2	3	4	5	6	7
26. The amount of variety in your work	1	2	3	4	5	6	7
27. Your job security	1	2	3	4	5	6	7
28. Taking everything into consideration, how do you feel about the job	1	2	3	4	5	6	7

	I'm extremely dis-satisfied	I'm very dis-satisfied	I'm moderately dis-satisfied	I'm not sure	I'm moderately satisfied	I'm very satisfied	I'm extremely satisfied
Please answer the next statements in relation to life in general							
29. The house or flat you live in	1	2	3	4	5	6	7
30. The local district you live in	1	2	3	4	5	6	7
31. Your standard of living, the things which you can buy and do	1	2	3	4	5	6	7
32. The way you spend your leisure time	1	2	3	4	5	6	7
33. Your present state of health	1	2	3	4	5	6	7
34. The education you have received	1	2	3	4	5	6	7
35. What you are accomplishing in life	1	2	3	4	5	6	7
36. What the future seems to hold for you	1	2	3	4	5	6	7
37. Your social life	1	2	3	4	5	6	7
38. Your family life	1	2	3	4	5	6	7
39. The present government	1	2	3	4	5	6	7
40. Freedom and democracy in Britain today	1	2	3	4	5	6	7
41. The state of law and order in Britain today	1	2	3	4	5	6	7
42. The moral standards and values in Britain today	1	2	3	4	5	6	7

	I'm extremely dis-satisfied	I'm very dis-satisfied	I'm moderately dis-satisfied	I'm not sure	I'm moderately satisfied	I'm very satisfied	I'm extremely satisfied
43. Britain's reputation in the world today	1	2	3	4	5	6	7
44. Taking everything together, your life as a whole these days	1	2	3	4	5	6	7

3. JOB CHARACTERISTICS

How much do the following aspects of work apply to your job?

The more you feel that a statement applies, the higher the number you circle. The less the statement applies, the lower the number you circle.

PLEASE ANSWER EVERY STATEMENT AND CIRCLE ONLY ONE NUMBER PER ITEM.

There are no right or wrong answers.

	There's none of that in my job	There's just a little of that	There's a moderate amount in my job	There's quite a lot in my job	There's a great deal in my job
Answer the next statements in relation to your current job (or last job if you are not in a paid job at present)					
45. The freedom to choose your own method of working	1	2	3	4	5
46. The amount of responsibility you are given	1	2	3	4	5
47. The recognition you get for good work	1	2	3	4	5
48. Being able to judge your work performance right away, when actually doing the job	1	2	3	4	5
49. Your opportunity to use your abilities	1	2	3	4	5
50. The amount of variety in your job	1	2	3	4	5

	There's none of that in my job	There's just a little of that	There's a moderate amount in my job	There's quite a lot in my job	There's a great deal in my job
51. Your chance of promotion	1	2	3	4	5
52. The attention paid to suggestions you make	1	2	3	4	5
53. The feeling of doing something which is not, trivial, but really worthwhile	1	2	3	4	5
54. Doing a whole and complete piece of work	1	2	3	4	5

How important are the following to you when looking for a job?

	Not at all important	Not particularly important	I'm not sure about its importance	Moderately important	Fairly important	Very important	Extremely important
55. Using your skills	1	2	3	4	5	6	7
56. Achieving something that you personally value	1	2	3	4	5	6	7
57. The opportunity to make your own decisions	1	2	3	4	5	6	7
58. The opportunity to learn new things	1	2	3	4	5	6	7
59. Challenging work	1	2	3	4	5	6	7
60. Extending your range of abilities	1	2	3	4	5	6	7

4. GENERAL CONCERNS

Most people these days have something to worry about, sometimes big things, sometimes small things. Please think back over the past few weeks and answer the following.

The more worried you have felt, the higher the number you circle. The less worried you have felt, the lower the number you circle.

PLEASE ANSWER EVERY SENTENCE AND CIRCLE ONLY ONE NUMBER PER ITEM

Remember, there are no right or wrong answers.

	Not at all concerned	Just a little concerned	Mildy concerned	Worry a little	Quite worried	Very worried	Extremely worried
61. Not having enough money for day to day living	1	2	3	4	5	6	7
62. Your immediate family	1	2	3	4	5	6	7
63. Your health	1	2	3	4	5	6	7
64. Growing old	1	2	3	4	5	6	7
65. How things are going at work	1	2	3	4	5	6	7
66. Britain's economic future	1	2	3	4	5	6	7
67. In general, how worried or concerned do you feel these days?	1	2	3	4	5	6	7

Taking all things together, how would you say things were these days?

Would you say you are:

	Very happy	3)	
	Fairly happy	2)	circle appropriate number
	Not too happy	1)	

THANK YOU FOR TAKING THE TIME TO ANSWER THIS QUESTIONNAIRE. ALL INFORMATION WILL BE TREATED AS CONFIDENTIAL

PLEASE DO NOT PUT YOUR NAME ON THE DOCUMENT.

II.VI. Clinical Data Schedule

FOR OFFICE USE

INITIAL FRACTURE CLASSIFICATION

Severity:

simple	1	
compound	2	grade
not known	9	

Site:

upper 33% length	1
mid 34-66% length	2
lower 67% + length	3
not known	9

13 14

15

Initial displacement:

none	1
less than 50%	2
50% or more	3
not known	9

Angulation:

(specify in degrees)

☐☐☐ ^{0}

16 18

19

Pattern of fracture:

transverse (less than 20^{o} angle)	1
oblique (20^{o} angle or greater)	2
spiral	3
double (any combination)	4
comminuted (1 or more fragments)	5
not known	9

20

Degree of comminution 'Hansen 1984):

I	(1 small fragment)	1
II	(50% cortex intact)	2
III	(less than 50% cortex intact)	3
IV	(no abutment of cortices)	4
not known		9

n/a 8

21

Velocity of injury:

low	1
high	2
not known	9

Associated fibular fracture:

no	
yes	same level / diff level / n/k
n/a	
n/k	

22 23 24

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Associated injuries:

	no	yes	not known		
skin injury/deficit	1	2	9		25
neurological deficit					26
tendonous injury					27
ligamentous injury					28
vascular injury					29
other (specify)	1	2	9		30

....

OTHER INJURIES (in addition to above)

List other main injuries ....

....

Summary table of other injuries:

	not applic	#	disloc	vasc	neuro	con-cuss	n/k		
head	8	1			4		9		31
upper limb: ipsilat.	8	1	2	3	4		9		32
contralat.									33
lower limb: ipsilat.									34
contralat.									35
spine									36
pelvis									37
other (specify)	8	1	2	3	4		9		38

....

KNOWN MEDICAL HISTORY

Existing medical conditions prior to admission:

none	1	cardiac	0	sensory	5
yes	2	respir.	1	psychol.	6
not known	9	locom./skeletal	2	other (specify)	7
		C.N.S.	3	....	
		endocr.	4	not known	9

39

40

n/a 8

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TREATMENT SUMMARY

Initial fixation:

		GIVE DATE(S)
cast only	1	....
MUA & cast	2	....
external fixator (specify)	3	....
internal fixation (specify)	4	....
other (specify)	5	....
not known	9	

24 25 days post injury

26

Subsequent fixation(if required):

		GIVE DATE(S)
none required	0	
remanipulation	1	....
external fixator (specify)	2	....
internal fixation (specify)	3	....
graft	4	....
other (specify)	5	....
not known	9	

wks post injury

1st 27 28 29

2nd n/a 8 30 31 32

wks post injury

Other comments:

....

....

....

....

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If cast applied:

date remove

not known 9

wks post # n/a 8 — 33 34

Mobilisation:

		not applicable	not known		
Date non-weight bearing		8	9	wks post #	35 36
Date partial-weight bearing		8	9		37-38
Date full-weight bearing			9		39-40

COMPLICATIONS	no	yes	not known	IF YES GIVE DATE/S	
compartment syndrome	1	2	9	....	41
ischaemic contractive				....	42
skin problems				....	43
clinical infection				....	44
shift/angulation				....	45
refracture				....	46
delayed/non-union				....	47
other (specify)				....	48

....

none 0
1 & over 1
n/k 9 — 49

CLINICAL RESULT

Union:

ununited 1

united 2 — date confirmed

not known 9

wks post # n/a 8 — 50 — 51 52

Shortening: (X-ray measurement of overlap)

none 0

shortening cms — 53 54

not known 9

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Alignment:

Valgus	☐☐☐ degrees		55 56 57 ☐☐☐
Varus	☐☐☐ degrees		☐☐☐ 58-60
Rotation	☐☐☐ degrees		☐☐☐ 61-63

Malunion:

no	1 ☐		
yes(specify)	2 ☐	....	64 ☐
not known	9 ☐		

Venuos stasis:

no	1 ☐		
yes (specify)	2 ☐	....	65 ☐
not known	9 ☐		

Oedema:

no	1 ☐		
yes (specify)	2 ☐	....	66 ☐
not known	9 ☐		

Comments:

....

....

....

....

....

....

Signature .... Date..........................

II.VII. Project Summary

DEPARTMENT OF ORTHOPAEDIC SURGERY

&

REHABILITATION STUDIES UNIT

PROSPECTIVE STUDY OF LONG-BONE FRACTURES OF THE LEG

The time taken for a fracture to heal varies from person to person and is affected by many other factors such as age and fracture type.

In order to study the recovery made by different people, a team from the University of Edinburgh is planning to follow the progress of everyone admitted to the Royal Infirmary with a femoral or tibial fracture. For each patient included in the study this will involve:

a) an interview while in hospital
b) a clinic/home interview 4 months after injury
c) a home interview 9 months after injury

The success of the study will depend upon the patients' co-operation, especially over the timing of appointments. It is therefore **VERY IMPORTANT** that patients let us know quickly if there are special reasons why they can not attend an appointment.

The results of the study will not be known until late 1987. At that time a summary of the work will be available, on request, to people who have taken part. It is therefore important that we are kept informed of any change of address both during the study and afterwards.

Finally, if there are any questions which you have about appointments or comments you wish to make during the study, please contact:-

Hilary Watson,
Rehabilitation Studies Unit,
3 Lauriston Park,
EDINBURGH EH3 9JA TEL: 031- 228 2666

THANK YOU FOR YOUR HELP

II.VIII. Consent Form

DEPARTMENT OF ORTHOPAEDIC SURGERY

&

REHABILITATION STUDIES UNIT

PROSPECTIVE STUDY OF LONG-BONE FRACTURES OF THE LEG

I, ... (print name) of ....

....(address).

Tel no. ....

am willing to take part in the above study.

Details of the research have been explained to me by ....

SIGNATURE .... DATE ....
(of patient)

SIGNATURE .... DATE ....

II.IX. Follow-up Letter

Rehabilitation Studies Unit
University of Edinburgh
3 Lauriston Park
Edinburgh EH3 9JA

Telephone: 031 228 2666/7/8

Dear

PROSPECTIVE STUDY OF LONG-BONE FRACTURES OF THE LEG

It is now approximately four months since you were admitted to the Royal Infirmary with a fracture of the leg.

As you may recall, you agreed to participate in the above study and I should therefore like to visit you at home in order to find out about the progress which you have made to date.

I should like to visit you on .... (day), ...

at .... am/pm for approximately one hour.

Please would you let me know alternative dates and times if this is NOT convenient.

I look forward to seeing you again soon.

Thanking you for your help,

Yours sincerely,

Hilary Watson
Research Associate

III. Supplementary Analysis

III.I. Reliability Data

Table A: Intra-rater Agreement for Need to Perform Functional Movements

Variable label	Intra-rater agreement: Work (N=77) %	phi	Other (N=97) %	phi	Both (N=99) %
Awkward postures	82	(0.63)	64	(0.27)	59
Prolonged: standing	84	(0.70)	75	(0.50)	66
sitting	78	(0.53)	70	(0.41)	59
kneeling	88	(0.77)	70	(0.31)	63
Stooping/crouching	86	(0.59)	87	(0.71)	77
Extensive walking	79	(0.55)	88	(0.57)	73
Slopes/gradients	73	(0.44)	88	(0.06)	71
Crossing difficult ground	78	(0.55)	91	(0.35)	76
Running	91	(0.73)	79	(0.47)	75
Jumping	78	(0.51)	81	(0.61)	68
Climbing: stairs	79	(0.56)	96	(0.48)	83
ladders	90	(0.79)	82	(0.56)	77
natural objects	79	(0.59)	69	(0.26)	61
Lifting/carrying	95	(0.79)	69	(0.20)	66
Transfers: sit/stand	74	(0.17)	93	(0.03)	76
stand/crouch	81	(0.57)	67	(0.35)	61
sit/ground	78	(0.35)	73	(0.23)	68
Transport: public	83	(0.65)	86	(0.68)	74
private	82	(0.61)	89	(0.46)	77
Foot/leg: controls	94	(0.81)	94	(0.60)	71
action	95	(0.02)	90	(0.59)	88

III.II. Differences between Patients with Tibial and Femoral Shaft Fractures

Table A: Bone by Age Groups

Age group	Tibia	Femur	Total
16 to 20 yrs	25	10	35
21 to 29 yrs	34	7	41
30 yrs and over	31	5	36
Total	90	22	112

Chi square = 2.69, 2d.f., p = 0.26 (not significant)

Table B: Bone by Sex

Sex	Tibia	Femur	Total
Male	75	15	90
Female	15	7	22
Total	90	22	112

Chi-square = 1.70, 1 d.f., p = 0.19 (not significant)

Table C: Bone by Leg

Leg	Tibia	Femur	Total
Right	50	9	59
Left	40	13	53
Total	90	22	112

Chi-square = 0.99, 1 d.f., p = 0.32 (not significant)

Table D: Bone by Site

Leg	Tibia	Femur	Total
Upper 33%	9	5	14
Mid 34-66%	24	12	36
Lower 67%+	54	5	59
Total	87*	22	109*

*3 double fractures excluded

Chi-square = 10.98, 2 d.f., p = 0.004 (significant)

Table E: Bone by Severity of Injury

Severity	Tibia	Femur	Total
Simple	70	17	87
Compound	20	5	25
Total	90	22	112

Chi-square = 0.00, 1 d.f., p = 1.00 (not significant)

Table F: Bone by Alcohol Consumption Noted prior to Admission

Alcohol	Tibia	Femur	Total
Not mentioned	71	16	87
Mentioned	19	4	23
Total	90	20*	110*

*2 missing

Chi-square = 0.0, 1 d.f., p = 1.00 (not significant)

Table G: Bone by Road Traffic Injury

RTA	Tibia	Femur	Total
No	65	6	71
Yes	25	16	41
Total	90	22	112

Chi-square = 13.52, 1 d.f., p<0.0002 (significant)

Table H: Bone by Employment Status

Employment	Tibia	Femur	Total
No	20	6	26
Yes	70	16	86
Total	90	22	112

Chi-square = 0.05, 1 d.f., p = 0.83 (not significant)

Table I: Bone by Weight Bearing at 16 weeks

Weight Bearing	Tibia	Femur	Total
Non/Partial	18	5	23
Full	68	15	83
Total	86	20	106*

*6 missing

Chi-square = 0.01, 1 d.f., p = 0.93 (not significant)

Table J: Bone by Return to Work at 16 weeks

Work status	Tibia	Femur	Total
Still off	51	11	66
Returned	18	4	22
Total	69	15	84

Chi-square = 0.07, 1 d.f., p = 0.78 (not significant)

Table K: Bone by Return to Work at 38 weeks

Work status	Tibia	Femur	Total
Still off	12	4	16
Returned	56	9	65
Total	68	13	81*

*5 missing

Chi-square = 0.50, 1 d.f., p = 0.48 (not significant)

Table L: Bone by Ability to Run at 16 weeks

Running ability	Tibia	Femur	Total
Able	4	-	4
Difficult/unable	57	17	74
Total	61	17	78*

*Excludes missing data and those who reported they never ran

Chi-square can not be computed

Table M: Bone by Ability to Run at 38 weeks

Running ability	Tibia	Femur	Total
Able	30	4	34
Difficult/unable	39	13	52
Total	69	17	86*

*Excludes missing data and subjects who reported they never ran

Chi-square = 1.51, 1 d.f., p = 0.22 (not significant)

Table N: Bone by Opinion of Recovery at 16 weeks

Opinion	Tibia	Femur	Total
Dissatisfied/unsure	29	5	34
Satisfied	56	15	71
Total	85	20	105*

*7 missing

Chi-square = 0.27, 1 d.f., p = 0.60 (not significant)

Table O: Bone by Opinion of Recovery at 38 weeks

Opinion	Tibia	Femur	Total
Dissatisfied/unsure	11	5	16
Satisfied	66	14	80
Total	77	19	96*

*16 missing

Chi-square = 0.84, 1 d.f., p = 0.36 (not significant)

Table P: Bone by Personal Injury Claim

Claim	Tibia	Femur	Total
No	67	9	76
Yes	18	11	29
Total	85	20	105

Chi-square = 7.65, 1 d.f., p = 0.006 (significant)

Table Q: Bone by Time to Union

Union	Tibia	Femur	Total
Up to 26 weeks	38	3	41
27 weeks and over	32	8	40
Total	70	11	81*

*31 missing

Chi-square = 1.79, 1 d.f., p = 0.18 (not significant)

III.III. Recovery at 16 and 38 weeks Following Fracture

Table A: Pain when Walking 16 weeks Following Injury by Personal Injury Claim

Pain	Insurance Claim No	Yes	Total
No	31	11	42
Occasionally	36	13	49
Yes	6	5	11
Total	73	29	102

Chi-square = 1.76, 2 d.f., p = 0.42 (not significant)

Table B: Reported Pain when Walking 38 weeks following Injury by Personal Injury Claim

Pain	Insurance Claim No	Yes	Total
No	46	12	58
Occasionally	22	9	31
Yes	2	7	9
Total	70	28	98

Chi-square = 12.45, 2 d.f., p = 0.002 (significant)

Table C: Reported Pain when at Rest 16 weeks following Injury by Personal Injury Claims

Pain	Insurance Claim No	Yes	Total
No	52	17	69
Occasionally	19	10	29
Yes	2	2	4
Total	73	29	102

Chi-square = 1.92, 2 d.f., p = 0.38 (not significant)

Table D: **Reported Pain when at Rest 38 weeks Following Injury by Personal Injury Claim**

	Insurance Claim		
Pain	No	Yes	Total
No	54	17	71
Occasionally	15	8	23
Yes	1	3	4
Total	70	28	98

Chi-square = 5.41, 2 d.f., p = 0.07 (not significant)

Table E: **Reported Pain Affecting Sleep 16 weeks Following Injury by Personal Injury Claim**

	Insurance Claim		
Pain	No	Yes	Total
No	61	19	80
Yes	12	10	22
Total	73	29	102

Chi-square = 3.00, 1 d.f., p = 0.08 (not significant)

Table F: **Reported Pain Affecting Sleep 38 weeks Following Injury by Personal Injury Claim**

	Insurance Claim		
Pain	No	Yes	Total
No	63	24	87
Yes	7	4	11
Total	70	28	98

Chi-square = 0.06, 1 d.f., p = 0.80 (not significant)

III.IV. Reported Ability to Perform Required Functions at 38 weeks Following Injury in Relation to Physiotherapy Treatment

Table A: Ability to Maintain Awkward Postures/Balance by Treatment

	Treatment		
Ability	No	Yes	Total
Able	33	23	56
Difficult	8)	8)	16)
Unable	2)^{10}	6)^{14}	8)^{24}
Total	43	37	80

Chi-square = 1.38, 1 d.f., p = 0.24 (not significant)

Table B: Abililty to Kneel by Treatment

	Treatment		
Ability	No	Yes	Total
Able	19	11	30
Difficult	5	10	15
Unable	11	5	16
Total	35	26	61

Chi-square = 4.83, 2 d.f., p = 0.09 (not significant)

Table C: Ability to Stoop by Treatment

	Treatment		
Ability	No	Yes	Total
Able	41	27	68
Difficult	9)	10)	19)
Unable	2)^{11}	5)^{15}	7)^{26}
Total	52	42	94

Chi-square = 1.79, 1 d.f., p = 0.181 (not significant)

Table D: Ability to Walk Extensively by Treatment

Ability	Treatment No	Treatment Yes	Total
Able	39	31	70
Difficult	8)	6)	14)
Unable	–)^{8}	5)^{11}	5)^{19}
Total	47	42	89

Chi-square = 0.63, 1 d.f., p = 0.43 (not significant)

Table E: Ability to Negotiate Slopes by Treatment

Ability	Treatment No	Treatment Yes	Total
Able	40	30	70
Difficult	12)	12)	24)
Unable	1)^{13}	1)^{13}	2)^{26}
Total	53	43	96

Chi-square = 0.16, 1 d.f., p = 0.69 (not significant)

Table F: Ability to Negotiate Difficult Ground by Treatment

Ability	Treatment No	Treatment Yes	Total
Able	38	23	61
Difficult	13)	16)	29)
Unable	2)^{15}	4)^{20}	6)^{35}
Total	53	43	96

Chi-square = 2.66, 1 d.f., p = 0.103 (not significant)

Table G: Ability to Run by Treatment

Ability	Treatment No	Yes	Total
Able	21	13	34
Difficult	15	9	24
Unable	13	15	28
Total	49	37	86

Chi-square = 1.89, 2 d.f., p = 0.39 (not significant)

Table H: Ability to Jump by Treatment

Ability	Treatment No	Yes	Total
Able	20	11	31
Difficult	10	9	19
Unable	14	10	24
Total	44	30	74

Chi-square = 0.71, 2 d.f., p = 0.70 (not significant)

Table I: Ability to Climb Stairs by Treatment

Ability	Treatment No	Yes	Total
Able	47	35	82
Difficult	8	8	16
Unable	-	-	-
Total	55	43	98

Chi-square = 0.07, 1 d.f., p = 0.79 (not significant)

Table J: Ability to Climb Ladders by Treatment

Ability	Treatment No	Treatment Yes	Total
Able	23	19	42
Difficult	3)	3)	6)
Unable	4)^{7}	5)^{8}	9)^{15}
Total	30	27	57

Chi-square = 0.06, 1 d.f., p = 0.81 (not significant)

III.V. Spearman Correlation Coefficients for Reduced Joint Range versus Functional Ability Variables

(16 weeks post-injury)

Table A: Knee Flexion by Functional Ability

Function	N	rho	p
Awkward postures	75	0.39	<0.001*
Prolonged kneeling	62	0.42	<0.001*
Stooping/crouching	89	0.32	0.001*
Extensive walking	90	0.33	0.001*
Slopes/gradients	91	0.22	0.019*
Crossing difficult ground	94	0.31	0.001*
Running	74	0.31	0.003*
Jumping	67	0.28	0.010*
Climbing: stairs	96	0.14	0.083
ladders	43	0.40	0.004*

* statistically significant

Table B: Knee Extension by Functional Ability

Function	N	rho	p
Awkward postures	75	0.12	0.146
Prolonged kneeling	62	0.20	0.063
Stooping/crouching	89	0.17	0.054
Extensive walking	90	0.21	0.025*
Slopes/gradients	91	0.29	0.003*
Crossing difficult ground	94	0.12	0.117
Running	74	0.14	0.116
Jumping	67	0.08	0.252
Climbing: stairs	96	0.12	0.124
ladders	43	0.42	0.002*

* statistically significant

Table C: Dorsiflexion by Functional Ability

Function	N	rho	p
Awkward postures	57	0.27	0.022*
Prolonged kneeling	50	0.18	0.100
Stooping/crouching	69	0.26	0.015*
Extensive walking	71	0.17	0.073
Slopes/gradients	71	0.19	0.054
Crossing difficult ground	72	0.31	0.004*
Running	60	0.16	0.108
Jumping	56	0.24	0.037*
Climbing: stairs	74	0.47	0.346
ladders	35	0.16	0.183

* statistically significant

Table D: Plantarflexion by Functional Ability

Function	N	rho	p
Awkward postures	57	0.20	0.066
Prolonged kneeling	50	0.25	0.039*
Stooping/crouching	69	0.18	0.074
Extensive walking	71	0.12	0.155
Slopes/gradients	71	0.19	0.060
Crossing difficult ground	72	0.21	0.035*
Running	60	0.11	0.200
Jumping	56	0.06	0.339
Climbing: stairs	74	0.25	0.018*
ladders	35	0.18	0.156

* statistically significant

III.VI. Psychological Normative Data

Table A: Normative Data for the Work and Life Attitude Scales

	Blue collar workers*		Fracture subjects 16 weeks**		38 weeks***	
Sub-scale item	x	sd	x	sd	x	sd
Work involvement	32.8	5.9	32.0	6.3	32.0	6.4
Intrinsic job motivation	36.3	5.5	35.4	6.6	34.8	5.6
Job satisfaction	70.5	15.4	71.2	15.0	68.5	15.0
Overall job satisfaction	5.3	1.4	5.3	1.6	5.0	1.5
Life satisfaction	67.1	11.4	67.0	11.3	66.3	11.7
Overall life satisfaction	5.1	1.3	5.2	1.3	5.1	1.1
Perceived intrin. job char.	32.7	8.4	31.8	7.4	30.4	8.9
Higher order needs strength	35.3	5.8	34.2	6.1	33.4	6.6
Self-rated anxiety	18.6	7.2	19.6	6.2	17.4	6.6
Overall anxiety	3.4	1.6	3.5	1.6	3.0	1.4
Happiness	-	-	2.0	0.5	2.0	0.5

* N = 590
** N = 71
*** N = 58

III.VII. Spearman's Rank Order Correlation Co-efficients

Table A: Association between Certain Variables and Aspects of Outcome

	Union			Return to work			HLC (9mths)			Kneeling (9mths)		
	N	rho	p	N	rho	p	N	rho	p	N	rho	p
Sex	81	0.07	0.28	64	-0.66	0.33	97	0.06	0.28	66	0.24	0.03
Hour (admiss)	77	0.05	0.32	60	0.20	0.06	91	0.10	0.17	62	0.03	0.42
Leg	81	-0.01	0.46	64	0.00	0.50	97	<0.01	0.47	66	-0.12	0.16
Bone	81	-0.15	0.08	64	0.10	0.21	97	0.04	0.34	66	0.07	0.33
Age	81	0.12	0.13	64	<0.01	0.49	97	-0.03	0.18	66	0.26	0.02
Social class	81	-0.03	0.38	64	0.28	0.02	97	-0.10	0.16	66	0.21	<0.05
Alco. consumpt.	81	0.06	0.29	64	0.06	0.32	97	-0.02	0.43	66	-0.08	0.26
Place of injury	81	<0.01	0.50	64	0.09	0.24	97	0.14	0.08	66	0.17	0.09
Driver/pass.	18	0.24	0.17	10	-0.20	0.29	24	0.12	0.30	16	0.02	0.47
Circ of injury	81	0.08	0.23	64	0.37	<0.01	97	0.11	0.15	66	0.06	0.31
Home ownership	81	0.01	0.48	64	0.13	0.15	97	0.02	0.41	66	0.19	0.06
Employment	81	-0.13	0.13	64	0.00	0.50	97	0.02	0.41	66	0.10	0.22
No.yrs in job	63	0.16	0.11	64	0.36	0.39	97	<0.01	0.49	51	0.04	0.39
Immobilisation	80	0.28	<0.01	64	0.34	<0.01	97	0.09	0.18	66	0.28	0.01
Type of cast	30	-0.05	0.40	18	0.38	0.06	32	0.17	0.18	22	-0.20	0.19
Pain on walking	77	0.30	<0.01	62	-0.04	0.39	96	0.14	0.08	66	0.20	0.05
Pain at rest	77	0.07	0.28	62	-0.16	0.11	96	-0.03	0.38	66	0.11	0.19
Pain (sleep)	77	0.20	0.04	62	-0.15	0.12	96	<0.01	0.47	66	0.11	0.21
Physiotherapy	78	0.02	0.43	62	-0.17	0.09	97	<0.01	0.47	66	-0.14	0.13
Contact GP	78	-0.06	0.30	62	0.22	0.04	97	0.11	0.14	66	0.05	0.34
Personnel man.	60	0.07	0.31	60	0.03	0.40	75	<0.01	0.49	47	-0.02	0.44
Line manager	60	-0.01	0.47	60	0.03	0.41	75	0.10	0.20	47	<0.01	0.50
Co-workers	60	0.08	0.27	60	0.00	0.47	75	0.08	0.24	47	-0.12	0.21
Tenderness	51	0.20	0.08	47	0.06	0.34	67	0.04	0.38	47	0.14	0.18
Muscle wasting	51	0.08	0.28	46	-0.02	0.45	66	0.10	0.22	49	0.14	0.17
Real shortening	50	-0.13	0.18	45	0.20	0.10	65	-0.25	0.42	46	0.08	0.31
Severity	81	0.21	0.03	64	0.43	<0.01	97	0.01	0.45	66	0.21	0.04
Grade of comp.	14	0.34	0.12	9	0.16	0.34	16	0.42	0.06	16	0.31	0.12
Site	81	<0.01	0.48	64	0.05	0.35	97	-0.18	0.04	66	0.21	0.04
Angulation	78	0.10	0.20	57	0.32	<0.01	88	0.01	0.46	57	0.20	0.07
Initial displ'mt	80	0.13	0.12	60	0.20	0.07	92	-0.17	0.05	60	0.11	0.20
Pattern of	81	0.15	0.09	63	0.06	0.32	96	0.33	<0.01	65	0.29	0.01
Fibular	70	0.34	<0.01	53	0.41	<0.01	77	-0.17	0.07	78	0.15	0.09
Treatment 1	81	0.34	<0.01	64	0.18	0.08	97	-0.07	0.23	66	0.18	0.08
Days to T1	81	0.07	0.26	63	0.74	0.28	96	0.03	0.38	65	0.21	<0.05
Treatment 2	42	0.38	0.05	28	0.27	0.09	51	0.17	0.12	51	0.12	0.20
Wks to T2	42	0.33	0.07	28	0.13	0.25	51	0.14	0.17	51	-0.09	0.26
Treatment 3	12	-0.36	0.13	6	0.12	0.41	13	0.04	0.44	13	0.40	0.09
Wks to T3	12	0.41	0.09	6	0.07	0.45	13	0.12	0.34	13	0.01	0.49
Wk cast off	62	0.42	<0.01	46	0.40	<0.01	64	0.11	0.18	41	0.42	<0.01
Week p.w.b.	70	0.25	0.02	52	0.18	0.10	80	0.02	0.42	50	0.22	0.06

contin.

	Union			Return to work			HLC (9mths)			Kneeling (9mths)		
	N	rho	p	N	rho	p	N	rho	p	N	rho	p
Infection	81	0.23	0.02	61	0.06	0.34	93	-0.04	0.36	63	0.12	0.17
Shift	81	0.12	0.17	61	0.05	0.34	93	-0.04	0.36	63	0.17	0.10
Delay	81	0.29	<0.01	61	0.20	0.06	93	0.15	0.08	63	0.30	<0.01
Opinion of recovery	77	-0.18	0.06	62	-0.07	0.30	96	-0.09	0.18	66	-0.43	<0.01
I-score	81	-0.21	0.03	64	-0.11	0.19	96	0.31	<0.01	66	0.02	0.43
E-score	81	0.04	0.35	64	0.27	0.02	97	0.30	<0.01	66	0.21	-0.05
HLC	81	-0.09	0.22	64	0.11	0.19	97	0.42	<0.01	66	0.08	0.26
Work involvmt.	56	--	--	49	-0.04	0.40	67	0.01	0.47	44	-0.27	0.04
Intrin. job motiv.	56	0.07	0.29	49	0.04	0.40	67	-0.14	0.13	44	-0.25	0.05
Job satis.	56	-0.02	0.46	48	0.05	0.37	66	-0.05	0.34	43	-0.44	<0.01
Overall job satis.	56	-0.11	0.20	49	0.05	0.36	67	0.06	0.32	44	-0.25	0.05
Life satis.	56	-0.06	0.34	49	-0.04	0.38	67	0.02	0.43	44	-0.21	0.09
Overall life satis.	55	-0.16	0.13	49	-0.06	0.35	67	0.16	0.10	44	-0.17	0.13
Perc.Intrin.j.cha.	56	-0.10	0.23	49	-0.25	0.04	66	0.01	0.46	44	-0.44	<0.01
Higher order n.s.	56	0.20	0.07	49	-0.08	0.30	67	-0.30	<0.01	43	0.04	0.41
Self-rated anxiety	56	-0.02	0.44	49	-0.10	0.26	67	-0.17	0.09	44	-0.10	0.23
Overall anxiety	54	0.17	0.10	49	-0.02	0.45	67	-0.14	0.13	44	0.15	0.17
Happiness	58	-0.09	0.27	48	-0.38	<0.01	65	0.05	0.33	43	-0.32	0.02
Knee flexion	72	0.25	0.02	59	0.41	<0.01	89	0.14	0.10	62	0.42	<0.01
Knee extension	72	0.35	<0.01	59	0.18	0.08	89	0.04	0.37	62	0.20	0.06
Dorsiflexion	53	0.10	0.24	49	0.16	0.14	69	0.08	0.27	50	0.18	0.10
Plantarflexion	53	0.03	0.41	49	0.18	0.10	69	0.11	0.18	50	0.25	0.04
A'wk. postures	58	0.40	<0.01	49	0.40	<0.01	74	0.03	0.39	55	0.37	<0.01
Stooping/crouch	68	0.20	0.05	55	0.22	0.06	87	0.32	<0.01	65	0.47	<0.01
Ext. walking	71	0.27	0.01	56	0.19	0.08	88	0.15	0.09	62	0.52	<0.01
Slopes/gradients	72	0.20	0.04	56	<0.01	0.49	89	0.11	0.16	61	0.48	<0.01
Cross dif. ground	74	0.20	<0.05	59	0.25	0.03	92	0.13	0.12	65	0.53	<0.01
Running	54	0.40	<0.01	51	0.37	<0.01	74	0.13	0.14	52	0.58	<0.01
Jumping	50	0.22	0.07	47	0.30	0.02	67	0.13	0.14	48	0.47	<0.01
Climb: stairs	77	0.11	0.16	61	-0.15	0.12	95	0.15	0.07	66	0.29	<0.01
ladders	38	0.48	<0.01	29	0.63	0.00	44	-0.04	0.41	36	0.44	<0.01
Visiting friends	58	-0.24	0.03	52	-0.08	0.29	76	-0.17	0.07	49	-0.07	0.31
Clubs/pubs	77	-0.22	0.03	62	<0.01	0.49	96	-0.01	0.44	66	-0.18	0.08
Pass. m.bike	77	0.08	0.23	62	-0.18	0.08	96	0.01	0.45	66	-0.24	0.03
Pass. car	77	0.01	0.45	62	0.03	0.40	96	-0.12	0.13	66	-0.07	0.30
Driver m.bike	80	-0.07	0.26	64	0.15	0.11	96	0.07	0.24	66	-0.06	0.32
Driver car	80	0.05	0.33	64	-0.09	0.25	96	-0.09	0.19	66	-0.27	0.01
Football	80	-0.13	0.12	64	-0.22	0.04	97	-0.14	0.09	66	-0.18	0.08
Racket sports	80	0.01	0.46	64	0.00	0.50	97	0.11	0.14	--	--	--
Income	74	<0.01	0.48	61	-0.25	0.03	97	-0.09	0.20	64	-0.08	0.27
Insurance claim	79	0.08	0.26	64	0.13	0.15	97	0.23	0.01	67	0.15	0.12

IV. Bibliography

Aichroth P, Freeman MAR, Smillie IS, et al (1978) *A knee function assessment chart.* JBJS 60-B(3): 308-309.

Aitken RCB (1975) *New wine in old bottles.* Inaugural lecture No 58, University of Edinburgh.

Anastasi A (1966) *Psychological testing.* (2nd edition) New York, MacMillan.

Armitage P, Berry G (1987) *Statistical methods in medical research.* (2nd edition) Oxford, Blackwell Scientific Publications pp 421-439.

Antony G, Frost RB (1985) *Reappraisal of methods in clinical length measurements: the potential of current technology.* Med & Biol Eng & Comput 23: 171-177.

Auchincloss J M, Wall I (1982) *Scintigraphy in the evaluation of potential fracture healing: a clinical study of tibial fractures.* Br J of Radiology 55: 707-713.

Austin RT (1978) *Fractures of the tibial shaft: is medical audit possible?* Injury 9(2): 93-101.

Batten RL, Donaldson LJ, Aldridge MJ (1978) *Experience with the AO method in the treatment of 142 cases of fresh fracture of the tibial shaft treated in the UK.* Injury 10(2): 108-114.

Benedetti J, Yuen K, Young L (1985) Life tables and survival functions. In: BMDP *BMDP statistical software manual.* (Reprint) California, University of California Press.

BMDP (1985) *BMDP statistical software manual.* (Reprint) California, University of California Press.

Bolton B (1985) *Measurement in rehabilitation.* Annual Review of Rehab 4: 115-144.

Bone LB, Johnson KD (1986) *Treatment of tibial fractures by reaming and intramedullary nailing.* JBJS 68-A(6): 877-887.

Booker HA (1985) *Physiotherapy and progressive exercise training for chronic airflow limitation.* Unpublished MPhil thesis, Polytechnic of Central London.

Boone DC, Azen SP, Lin CM, et al *Reliability of goniometric measurements.* Phys Ther 58: 1355-1360.

Brinkmann JR, Perry J (1985) *Rate and range of knee motion during ambulation in healthy and arthritic subjects.* Phys Ther 65(7): 1055-1060.

Brown P, Urban JG (1969) *Early weight-bearing treatment of open fractures of the tibia. An end-result study of sixty-three cases.* JBJS 51-A(1): 59-75.

Brown SA, Major MB (1976) *Ultrasonic assessment of early callus formation.* Biomed Eng : 124-126.

Buijk CA (1986) *The development of a General Handicapped Attitude Scale*

(GHAS). Int J Rehab Res 9(1): 53-68.

Chan KM, Tse PYT, Chow YYN, et al (1984) *Closed medullary nailing for fractured shaft of the femur - a comparison between the Kuntscher and AO techniques.* Injury 15(6): 381-387.

Christensen J, Grieff J, Rosendahl S (1981) *Fractures of the shaft of the tibia treated with AO - compression osteosynthesis.* Injury 13(4): 307-14.

Cleak M (1985) *Getting the measure of muscle contraction.* Ther Weekly Nov 28: 10.

Coates H, King A (1982) *The patient assessment: a handbook for therapists.* Edinburgh, Churchill Livingstone.

Coleman V (1977) *Paper doctors: a critical assessment of medical research.* London, Temple Smith.

Connolly JF, Lafollette B (1973) *Closed reduction and early cast-brace ambulation in the treatment of femoral fractures.* JBJS, 55-A(8): 1581-1599.

Cornes P (1987) *Rehabilitation and return to work of personal injury claimants.* Unpublished PhD thesis, University of Edinburgh.

Crawford-Adams J (1983) *Outline of fractures.* Edinburgh, Churchill Livingstone.

Crewe NM, Athelston GT (1981) *Functional assessment in vocational rehabilitation: a systematic approach to diagnosis and goal setting.* Arch Phys Med Rehabil 62: 299-305.

Cunningham J, Amaning K, Harris D, et al (1986a) Vibration monitoring of fracture healing. In: *Annual Report of the Oxford Orthopaedic Engineering Centre.* Oxford, University of Oxford.

Cunningham J, Spriggins T, Beavis A, et al (1986b) Fracture stiffness monitoring. In: *Annual Report of the Oxford Orthopaedic Engineering Centre.* Oxford, University of Oxford.

De Bastiani G, Aldeqheri R, Reuzi Brivio L (1986) *Dynamic axial fixation. A rational alternative for the external fixation of fractures.* Int Orthop SICOT 10: 95-99.

De Haas WG, Beauvpre A, Cameron H, et al (1986) *The Canadian experience with pulsed magnetic fields in the treatment of ununited tibial fractures.* Clin Orthop Rel Res 208: 55-58.

Dehne E (1974) *Ambulatory treatment of the fractured tibia.* Clin Orthop Rel Res 105: 192-201.

Dencker H (1965) *Shaft fractures of the femur.* Acta Chir Scand 130: 173.

De Souza LJ (1987) *Healing time of tibial fractures in Ugandan Africans.* JBJS 69-B(1): 56.

Diem K, Lentner C eds (1970) *Documenta Geigy - scientific tables.* (7th edition) Switzerland, Ciba-Geigy Ltd.

Dugas R, D'Ambrosia R (1985) *The Grosse-Kempf interlocking nail: technique of femoral and tibial fractures.* Orthopaedics 8(11): 1363-1370.

Durham J, MacNeish A, Rooney PJ, et al (1985) *The MDR index of function in rheumatoid arthritis.* Clin & Exp Rheum 3: 297-302.

Ecosoft (1984) *MICROSTAT. An interactive general-purpose statistical package.* Release 4.0. Indianapolis, Ecosoft Inc.

Edwards RHT, Young A, Hosking GP, et al (1977) *Human skeletal muscle function: description of tests and normal values.* Clin Sci Mol Med 52: 283-90.

Ellis H (1956) *A study of some factors affecting prognosis following tibial shaft fractures.* M.Ch (Oxon) Thesis, Bodleian Library, Oxford.

Ellis H (1958a) *The speed of healing after fracture of the tibial shaft.* JBJS 40-B(1): 42-46.

Ellis H (1958b) *Disabilities after tibial shaft fractures.* JBJS 40-B(2): 190-197.

Ellis H (1964) *Treatment of fractures of the tibial shaft.* JBJS 46-B(3): 371-372.

Evans M (1986) Mk III external fixator-design considerations. In: *Annual Report of the Oxford Orthopaedic Engineering Centre.* Oxford, University of Oxford.

Feinstein AR, Josephy BR, Wells CK (1986) *Scientific and clinical problems in indexes of functional disability.* Annals of Internal Med 105(3): 413-420.

Ferguson GA (1976) *Statistical analysis in psychology and education.* (4th edition) Tokyo, McGraw-Hill Kogakusha Ltd.

Flamer S (1985) *Psychological outcomes of rehabilitation: some issues in selection and measurement.* Int Rehabil Med 7(4): 156-160.

Goldberg D (1979) *Manual of the General Health Questionnaire.* Windsor, Berkshire NFER.

Goodship AE, Kenwright J (1985) *The influence of induced micromovement upon the healing of experimental tibial fractures.* JBJS 67-B(4): 650-655.

Goodship AE, Kenwright J (1986) The effect of intermitent strain upon the healing of experimental tibial fractures. In: *Annual Report of the Oxford Orthopaedic Engineering Centre.* Oxford, University of Oxford.

Gossman MR, Rose SJ, Sahrmann SA, et al (1986) *Length and circumference measurements in one-joint and multi-joint muscles in rabbits after immobilisation.* Phys Ther 66(4): 516-520.

Gouvier DW, Richards JS, Blanton PD, et al (1985) *Dependent variables in rehabilitation research.* Arch Phys Med Rehabil 66(Dec): 803-805.

Granger CV, Albrecht GL, Hamilton BB (1979) *Outcome of comprehensive medical rehabilitation: measurement of PULSES profile and the Barthel Index.* Arch Phys Med Rehabil 60: 145-154.

Gregg PJ, Barsoum MK, Clayton CB (1983) *Scintigraphic appearance of the tibia in the early stages following fracture.* Clin Orthop 175: 139-146.

Guilford JP (1956) *Fundamental statistics in psychology and education.* Tokyo, McGraw-Hill Ltd.

Gustilo RB, Anderson JT (1976) *Prevention of infection in the treatment of one thousand and twenty-five open fractures of the long bones.* JBJS 58-A(4): 453-458.

Haines JF, Williams EA, Hargadon EJ, et al (1984) *Is conservative treatment of displaced tibial shaft fractures justified?* JBJS 66-B(1): 84-88.

Hammer RRR, Hammerby S, Lindholm B (1985a) *Accuracy of radiologic assessment of tibial shaft fracture union in humans.* Clin Orthop & Rel Res 199: 233-238.

Hammer RRR (1985b) *Strength of union in human tibial shaft fracture.* Clin Orthop & Rel Res 199: 226-232.

Hampton JR (1987) *The veteran's administration hypertension trial.* Hospital Update 13(11): 927-938.

Haskard DO, Silman AJ (1985) *Measuring devices for studying joint mobility in the normal population.* Eng in Medicine 14(2): 75-77.

Hicks A (1986) *Current healing.* Fracture Magazine 9:8-9.

Hicks JH (1977) *Rigid fixation as a treatment for hypertrophic non-union.* Injury 8(2): 199-205.

Hiorns RW, Newcombe F (1979) *Recovery curves: uses and limitations.* Int Rehabil Med 1(4):173-176.

Hoffmann W (1986) *Practice paradigms in service-delivery to persons with disabilities.* Rehab in S.A. Mar: 26-29.

Holbrook M, Skilbeck C (1983) *An activities index for use with stroke patients.* Age and Aging 12: 166-170.

Holdsworth FW (1942) *First principles of wound treatment.* The Lancet 1(6190): 474-475.

Hopkins A (1985) Survival analysis with covariates - Cox models. In: BMDP *BMDP statistical software manual.* (Reprint) California, University of California Press.

Huskisson EC (1974) *Measurement of pain.* The Lancet 2(7890): 1127-1131.

Hutchins PM (1981) *The outcome of severe tibial injury.* Injury 13(3): 216-219.

Hyde SA, Scott OM, Goddard CM (1983) *The myometer: the development of a clinical tool.* Physiotherapy 69(12): 424-427.

Jacelon CS (1986) *The Barthel Index and other indices of functional ability.* Rehab Nursing 11(4): 9-11.

Jacobs RR, Jackson RP, Preston DF, et al (1981) *Dynamic bone scanning in fractures.* Injury 12(6): 455-459.

Jochheim K-A, Koch M, Mittelsten Scheid E, et al (1984) *ERTOMIS Ability and requirement profiles aid for the vocational reintegration of the disabled.* Koln, ERTOMIS Bildings und Forderings-GMBH.

Johner R, Wruhs O (1983) *Classification of tibial shaft fractures and correlation with results after rigid internal fixation.* Clin Orthop & Rel Res 178: 7-25.

Johnson BL, Nelson JK (1979) *Practical measurements for valuation in physical education.* (3rd edition) Minnesota, Burgess Publishing Co.

Jones R (1912) *Present position of treatment of fractures.* BMJ II: 1589.

Jorgensen TE (1972) *Measurement of stability of crural fractures treated with Hoffman osteotaxis.* Acta Orthop Scand 43: 280.

Karlstrom G (1974) *Fractures of the tibial shaft - a critical evaluation of treatment alternatives.* Clin Orthop & Rel Res 105: 82-115.

Katz S, Ford AB, Moskowitz RW, et al (1963) *Studies of illness in the aged. The index of ADL: a standardized measure of biological and psychological function.* JAMA 185: 914-919.

Kay L, Hansen BA, Raaschou HO (1986) *Fractures of the tibial shaft conservatively treated.* Injury 17(1): 5-11.

Keele KD (1948) *The pain chart.* The Lancet 2(6514): 6.

Kempf I, Gross A, Beck G (1985) *Closed locked intramedullary nail.* JBJS 67-A(5): 709-720.

Kenwright J, Goodship AE, Kelly DJ et al (1986) *Effect of controlled axial micromovement on healing of tibial fractures.* The Lancet 2(8517): 1185-1187.

Kuhn TS (1970) *The structure of scientific revolutions.* (2nd edition) Chicago, University of Chicago Press.

Kuntscher G (1940) *Die Marknagelung von Knochenbruchen Tierexperimenteller Tiel.* Klin Wochenschr 19: 6-10.

Lavine LS, Grodzinski AJ (1987) *Current concepts review - electrical stimulation of repair of bone.* JBJS 64-A(4):626-630.

Lee PWH, Mak FL (1984) *Locus of Control, teachers' ratings and task performance of physically handicapped children.* The Exceptional Child 31(2): 128-133.

Lee RH (1979) *Recovery and rehabilitation after minor fractures.* Report of the Health Services Research Unit, No 36, University of Kent at Canterbury.

Lennmarken C, Bergman T, Larsson L-E (1985) *Skeletal muscle function in man: force, relaxation rate, endurance and contraction time dependence on sex and age.* Clin Physiol 5: 243-255.

Levin R, Devereux S (1986) *Surveying patient satisfaction by interviewing in person.* Dimensions June: 30-31.

Lindeque BGP, Schoeman HS, Dommisse GF, et al (1987) *Fat embolism and the fat embolism syndrome* JBJS 69-B(1): 128-131.

Lipton JP, Hershaft AM (1985) *On the widespread acceptance of dubious medical findings.* J Health & Soc Behav 26(Dec): 336-351.

McGavin CR, Gupta SP, McHardy GJR (1976) *Twelve-minute walking test for assessing disability in chronic bronchitis.* BMJ 1: 822-823.

McKibbins B (1978) *The biology of fracture healing in long bones.* JBJS 60-B(2): 150-162.

McLaughlin SJ, Chan STF, Ford D, et al (1987) *Microcompupter system for the analysis of muscle function.* J Biomed Eng 9: 59-63.

McMaster M (1976) *Disability of the hindfoot after fracture of the tibial shaft.* JBJS 58-B(1): 90-93.

Mahoney FI, Barthel DW (1965) *Functional evaluation: the Barthel Index.* Maryland State Med J 14: 61-65.

Matkin RE (1985) *Rehabilitation: an ambiguous term and an unfulfilled ideal.* Rehab Lit 46(11-12): 314-320.

Melzack R (1975) *The McGill pain questionnaire: major properties and scoring methods.* Pain 1: 277-299.

Melzack R, Torgerson WS (1971) *On the language of pain.* Anaesthesiology 34: 50-59.

Muller ME (1963) *Internal fixation for fresh fractures and for non-union.* Proc R Sec Med 56: 455.

Nachinocar VG, Vad MK (1985) *Functional evaluation of orthopaedically disabled and handicapped.* Rehab in Asia Aug: 9-25.

Neuromotor Group (1983) *Physiotherapy Motor Assessment Forms A & B.* Buckingham, Winslow Press.

Newman RJ, Duthie RB, Francis MJO (1985) *Nuclear magnetic resonance studies of fracture repair.* Clin Orthop & Rel Res 198: 297-303.

Nichols PJR (1979) *The practice of research in rehabilitation - a personal view.* Int Rehabil Med 1(2): 73-78.

Nicoll EA (1964) *Fractures of the tibial shaft.* JBJS 46-B (3): 373-387.

Norkin CC, White DJ (1985) *Measurement of joint motion: a guide to goniometry.* Philadelphia, FA Davis Co.

Olson RS (1985) *Normalization: a concept in analysis.* Rehab Nursing Nov/Dec: 22-23.

OPCS (1970) *Classification of Occupations.* London, HMSO.

Oppenheim AN (1966) *Questionnaire design and attitude measurement.* London, Heinemann.

Orenstein A, Phillips WRF (1978) *Understanding social research: an introduction.* Boston, Allyn and Bacon Inc.

Pagano RR (1981) *Understanding statistics in the behavioural sciences.* New York, West.

Pandya S, Florence JM, King WM, et al (1985) *Reliability of goniometric measurements in patients with Duchenne Muscular Dystrophy.* Phys Ther 65(9): 1339-1342.

Parker B (1974) *Two-plate fixation in the treatment of tibial shaft fracture and non-union.* Injury 5(4): 291-297.

Parry A (1980) *Physiotherapy assessment.* London, Croom Helm.

Partridge CP, Johnston M, Edwards S (1987) *Recovery from physical disability after stroke: normal patterns as a basis for evaluation.* The Lancet 1(8529): 373-375.

Partridge CP (1985) *Cognitions and emotions as predictors of recovery in conditions involving physical disability.* Unpublished Phd thesis, University of London.

Perry J (1985) *Scientific basis of rehabilitation.* Instr Course Lect 34: 385-388.

Puranen J, Punto L (1981) *Osteomedulloangiography: a method of estimating the consolidation prognosis of tibial shaft fractures.* Clin Orthop & Rel Res 161: 8.

Read M, Wade P (1984) *Sports injuries.* London, Breslich & Foss.

Roaas A, Andersson GBJ (1982) *Normal range of motion of the hip, knee and ankle joints in male subjects, 30-40 years of age.* Acta Orthop Scand 53: 205-208.

Robson C (1973) *Experiment, design and statistics in psychology.* Harmondsworth, Penguin Books Ltd.

Rokkanen P, Slatis P, Vankka E (1969) *Closed or open intramedullary nailing of femoral shaft fractures? A comparison with conservatively treated cases.* JBJS 51-B(2): 313-329.

Ross ERS (1984) Fractures - 1. Clinical In: Downie PA (ed) *Cash's textbook of orthopaedics and rheumatology for physiotherapists.* London, Faber & Faber pp 451-475.

Royal College of Physicians of London (1986) *Physical disability in 1986 and beyond.* J Royal College of Physicians of London. 20(3): 160-194.

Rudicel S, Esdaile J (1985) *The randomized clinical trail in orthopaedics: obligation or option?* JBJS 67-A(8): 1284-1293.

Rusk HA (1947) *Rehabilitation: the third phase of medical care.* New York Medicine 3(6): 15-18.

Safilios-Rothschild C (1970) *The sociology and social psychology of disability and rehabilitation.* New York, Random House.

St. Pierre RK, Fleming SS, Fleming LL (1982) *Fractures of the femoral shaft: a prospective study of closed intramedullary nailing, modified open intramedullary nailing and cast bracing.* Southern Med J 75(7): 827-835.

Sakellarides HT, Freeman PA, Grant BD (1964) *Delayed union and non-union of tibial shaft fractures.* JBJS 46-A(3): 557-569.

Sarmiento A (1967) *A functional below-the-knee cast for tibial fractures.* JBJS 49-A(5): 855.

Sarno JE, Sarno MT, Levita E (1973) *The functional life scale.* Arch Phys Med Rehabil 54:214-220.

Scranton PE, Whitesel JP, Farewell V (1985) *Cybex evaluation of the relationship between anterior and posterior compartment lower leg muscles.* Foot and Ankle 6(2): 85-89.

Scudder CL (1985) *The open or operative treatment of fresh fractures: is it ever justifiable?* Clin Orthop & Rel Res 19(1): 3-11.

Sepic SB, Murray MP, Mollinger LA, et al (1986) *Strength and range of motion in the ankle in two age groups of men and women.* Am J Phys Med 65(2): 75-84.

Sherman KP, Shakespeare DT, Nelson L, et al (1986) *A simple adjustable functional brace for tibial fractures.* Injury 17 (1): 15-18.

Siegel S (1956) *Nonparametric statistics for behavioural sciences.* Tokyo, McGraw-Hill Ltd.

Sinclair A, Whalley SP, Watson HJ (1984) *The rehabilitation and resettlement of occupationally disabled workers in the BSC with specific reference to Scunthorpe Works.* ECSC Report No 7247/18/047. London, British Steel Corporation.

Smith MA, Jones EA, Strachan RK, et al (1987) *Prediction of fracture healing in the tibia by quantitative radionuclide imaging.* JBJS 69-B(3): 441-447.

Snow M, Thurber S (1983) *Factorial validity of the Health Locus of Control (HLC)*

Scale. Ed & Psychol Measurement 43: 893-895.

Solheim K (1960) *Disabilities after shaft fractures of the bones of the leg. A clinical and radiographic follow-up study of 131 patients after approximately fifteen years.* Acta Clir Scand 119: 280-287.

Solheim K, Bo O (1973) *Intramedullary nailing of tibial shaft fractures.* Acta Orthop Scand 44: 323.

Sommerville JG (1970) *The impact of the rehabilitation services on sickness absenteeism.* Proc Roy Soc Med 63: 1146.

Souter WA (1969) *Autogenous cancellous strip grafts in the treatment of delayed union of long bone fractures.* JBJS 51-B(1) : 63.

SPSS (1986) *SPSSx User's guide.* (2nd edition) Chicago, SPSS Inc.

Stacey M (1969) *Methods of social research.* London, Pergamon Press.

Steen Jensen J, Johansen J, Mørch A (1977) *Middle third femoral fractures treated with medullary nailing or AO compression plates.* Injury 8(3): 174-181.

Stevenson JS, Bright RW, Dunson GL et al (1974) *Technetium - 99m phosphate bone imaging: a method for assessing bone graft healing.* Radiology 110: 391-394.

Strachan RK, Jones GA, Smith MA, et al (1983) *The prediction of non-union in tibial fractures using quatitative bone scanning and fracture shift.* Paper presented at the British Orthopaedic Research Society, Nottingham.

Talbot HS (1984) *A concept of rehabilitation.* Rehab Lit 45: 152-158.

Tallis R (1987) *Measurement in rehabilitation: an introduction.* Clin Rehab 1: 1-3.

Tarrier N, Maguire P, Kincey J (1983) *Locus of control and cognitive behaviour therapy with mastectomy patients: a pilot study.* Br J Med Psychol 56: 265-270.

Thompson AG, Batten RL (1977) *The application of rigid internal fixation to the treatment of non-union and delayed union using the AO technique.* Injury 8(3): 188-198.

Thompson CVS (1942) *History of surgical instruments.* London, Schuman's (also in Br J of Surgery).

Timm KE, Patch DG (1985) *Case study: use of Cybex II velocity spectrum in the rehabilitation of postsurgical knees.* J Orthop Sports Phys Ther 6(6): 347-349.

Towle J (1986) *The precise measurement of knee joint kinematics as an aid in clinical assessment.* Clin Biomech 1: 214-215.

Trueta J (1974) *Blood supply and the rate of healing of tibial fractures.* Clin Orthop & Rel Res 105: 11-26.

Urist MR, Johnson RW (1943) *Calcification and ossification, IV. Healing of fractures in man under clinical conditions.* JBJS 25(2): 375-426.

Wainapel SF, Kayne HL (1985) *Statistical methods in rehabilitation research.* Arch Phys Med Rehabil 66(May): 322-324.

Wall WD, Williams HL (1970) *Longitudinal studies and the social sciences. A Social Science Research Council review.* London, Heinemann.

Wallston BS, Wallston KA (1978) *Locus of control and health: a review of the literature.* Health Ed Monographs 6: 107-117.

Wallston BS, Wallston KA, Kaplan GD, et al (1976) *Development and validation of the Health Locus of Control (HLC) Scale.* J Consulting Clin Psychol 44(4): 580-585.

Warr P, Cook J, Wall T (1979) *Scales for the measurement of some work attitudes and aspects of psychological well-being.* J Occup Psychol 52: 129-148.

Watson HJ (1985) *Prospective study of tibial fractures - progress report 2.* Internal report of the Rehabilitation Studies Unit, University of Edinburgh.

Watson HJ (1987) *Occupational assessment: the Activity Matching Ability System (AMAS).* Int Disabil Studies J 9(2): 71-74.

Watson HJ, Cornes P (1986) Occupational assessment of people with disabilities. In: Kettle M, Massie B (eds) *Employers' Guide to Disabilities.* Cambridge, Woodhead-Faulkner.

Watson HJ, Strachan RK, Cornes P, et al (1984) *Prospective study of tibial fractures - proposed study design and procedure.* Internal report of Rehabilitation Studies Unit, University of Edinburgh.

Watson-Jones R, Coltart WD (1943) *Slow union of fractures with a study of 804 fractures of the shafts of the tibia and femur.* Br J of Surgery 30: 260-276.

Weisenberg M (1980) Measuring pain phenomena In: Rachman S (ed) *Contributions to Medical Psychology, Vol 2.* London, Pergamon Press pp 92-97.

Weller S (1983) *Bio-mechanical principles of osteosynthesis in fracture care.* Western Pacific Orthopaedic Association, XX(2): 1-8.

White AA (1975) *Fracture treatment. The still unsolved problem.* Clin Orthop & Rel Res 106: 279-284.

White GM, Healy WL, Brumback RJ, et al (1986) *The treatment of fractures of the femoral shaft with the Brooker-Willis distal locking intramedullary nail.* JBJS 68-A(6): 865-876.

Winefield HR, Cormack SM (1986) *Regular activities as indicators of subjective health status.* Int J Rehab Research 9(1): 47-52.

WHO (1977) *International Classification of Diseases, Volume 1.* London, HMSO.

WHO (1980) *International classification of impairments, disabilities and handicaps; a manual of classification relating to the consequencies of disease.* Geneva, WHO.

Wilcocks R (1979) *A vocational assessment and man-work procedure for the handicapped and disabled.* Unpublished MPhil thesis, University of Leeds.

Winquist RA, Hanson ST (1980) *Comminuted fractures of the femoral shaft treated by intramedullary nailing.* Orthop Clin North Am 2: 633-648.

Winquist RA, Hansen ST, Clawson DK (1984) *Closed intramedullary nailing of femoral fractures.* JBJS, 66-A(4): 529-539.

Wolf SL, Edwards DI, Shutter LA (1986) *Concurrent assessment of muscle activity (CAMA).* Phys Ther 66(2): 218-224.

Zeiderman M, Wilson IJ, Price R (1984) *An objective test of muscle function using the BBC microcomputer.* J Microcomput Appl 7: 309-317.

Zucman J, Maurer P (1970) *Primary medullary nailing of the tibia for fractures of the shaft in adults.* Injury 2(2): 84.